DATE	DOCKET NUMBER	PROCEEDINGS
04/12/2004	223	Minute Entry: Continued Court Trial held on 4/12/2004 before Phyllis J. Hamilton. Matter continued to 4/13/04 at 8:30 AM for Further Court Trial. (Court Reporter: Diane Skillman.) (lm, COURT STAFF) (Date Filed: 4/12/2004) (Entered: 04/12/2004)
04/13/2004	224	TRIAL MINUTES: Continued Bench Trial held on 4/13/2004 before Phyllis J. Hamilton. 4/26/04—Supplemental Findings. Matter was continued to 4/15/04 at 8:30 AM for Further Court Trial. (Court Reporter: Diane Skillman) (lm, COURT STAFF) (Date Filed: 4/13/2004) (Entered: 04/13/2004)
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04/15/2004	227	TRIAL MINUTES: Continued Court Trial held on 4/15/2004 before Phyllis J. Hamilton. Matter continued to 4/16/04 at 8:30 AM for Further Court Trial. (Court Reporter: Diane Skillman.) (lm, COURT STAFF) (Date Filed: 4/15/2004) (Entered 04/15/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
04/16/2004	228	TRIAL MINUTES: Bench Trial completed on 4/16/2004 before Phyllis J. Hamilton. (Court Reporter: Diane Skillman) (lm, COURT STAFF) (Date Filed: 4/16/2004) (Entered: 04/16/2004)
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04/23/2004	231	Proposed Findings of Fact by City and County of San Francisco City and County of San Francisco's Supplemental Findings of Fact and Conclusions of Law. (Van Runkle, Aleeta) (Filed on 4/23/2004) (Entered: 04/23/2004)
		* * * * *
04/26/2004	234	Proposed Findings of Fact by Planned Parenthood Federation of America, Inc., Planned Parenthood Golden Gate Supplemental Proposed Findings of Fact and Conclusions of Law. (Parker, Beth) (Filed on 4/26/2004) (Entered: 04/26/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
04/26/2004	235	Proposed Findings of Fact by John Ashcroft Defendant's Post-Trial Proposed Findings of Fact and Conclusions of Law. (Simpson, W.) (Filed on 4/26/2004) (Entered: 04/26/2004)
06/01/2004	236	ORDER GRANTING PERMANENT INJUNCTION; FINDINGS OF FACT AND CONCLUSIONS OF LAW IN SUPPORT THEREOF. Signed by Judge Hamilton on June 1, 2004. (pjhlc3,) (Filed on 6/1/2004) (Entered: 06/01/2004)
		* * * * *
08/02/2004	243	NOTICE OF APPEAL by John Ashcroft. Appeal Record due by 9/1/2004. (Attachments: # 1) (Simpson, W.) (Filed on 8/2/2004) (Entered: 08/02/2004)
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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

TRANSCRIPT OF PROCEEDINGS
Monday, Mar. 29, 2004
Volume 1

BEFORE THE HONORABLE
PHYLLIS J. HAMILTON, JUDGE

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* * * * *

[MAUREEN PAUL, M.D.—DIRECT EXAMINATION]

[6]

* * * * *

Q. Dr. Paul, are you board certified in any area?

A. Yes, in obstetrics and gynecology and also occupational and environmental medicine.

Q. And are you the chief medical officer at Planned Parenthood Golden Gate?

A. Yes, I am.

Q. What does that position entail?

A. The actual overseeing the quality of medical care at Planned Parenthood Golden Gate; providing direct clinical services, participating in strategic planning for the organization; hiring of the physicians to work at Golden Gate; and also supervising both the physicians and the advanced practice clinicians who work at Planned Parenthood Golden Gate, [7] as well as developing clinical protocols that we use in the clinics.

Q. At how many sites does Planned Parenthood Golden Gate provide medical services?

A. Eight.

Q. And where are those sites located, generally?

A. Throughout the San Francisco Bay area.

Q. And what medical services are available at Planned Parenthood Golden Gate?

A. Planned Parenthood Golden Gate provides primary health care services, in that we do general physical exams and take care of common health conditions that people may have. We also provide a broad range of reproductive health care services, including contraception and abortion, basic gynecological exams, pap tests, treatment of abnormal pap tests, diagnosis of and management of sexually-transmitted infections and HIV testing and referral.

Q. And are abortions available at all eight of the Planned Parenthood Golden Gate sites?

A. Yes.

Q. And to what gestational age are abortions performed at Planned Parenthood Golden Gate?

A. Eighteen weeks, six days of pregnancy.

Q. And what methods of abortion are available at Planned Parenthood Golden Gate?

[8]

A. We provide early medical abortion, vacuum aspiration abortion, and dilation and evacuation or D&E abortion.

Q. And you said that you currently provide abortions to 18 weeks, six days; is that correct?

A. That's correct.

Q. Is it your plan to increase the gestational age at which abortions are available at Planned Parenthood Golden Gate?

A. Yes.

Q. Now, in addition to your work as the chief medical officer Planned Parenthood Golden Gate, are you also an associate clinical professor in the Department of Obstetrics Gynecology and Reproductive Sciences at University of California at San Francisco?

A. Yes, I am.

Q. And what does that involve?

A. That involves teaching, and we are also setting up a collaborative research program between UCSF and Planned Parenthood Golden Gate. The teaching primarily involves early abortion methods.

Q. And are you also the director of training at the UCSF Center for Reproductive Health Research and Policy?

A. Yes, I am.

Q. And what does that involve?

A. That is the position that I hold where I do the training in early abortion, primarily for primary care residency programs, [9] such as family practice residency programs where building and training consortium, academic community collaboration to provide training to the residents and faculty in the primary care residency programs.

Q. And Dr. Paul, do you have clinical experience performing first-trimester abortions using both surgical and medical methods?

A. Yes, I do.

Q. Is that a significant part of your medical practice?

A. Yes, it is.

Q. And do you have clinical experience performing D&E abortions?

A. Yes, I do.

Q. And is that a significant part of your medical practice?

A. Yes, it is.

Q. And in your current practice to what gestational age do you personally perform D&E abortions?

A. I perform D&E abortions to 18 weeks, six days gestation.

Q. And at other times in your career have you performed D&E's to later gestational ages?

A. Yes, I have. During residency I performed D&E's to about 23 weeks gestation.

Q. And do you have clinical experience performing induction abortions?

A. Yes, I do.

[10]

Q. Do you perform induction abortions in your current practice?

A. No, I don't.

Q. When did you perform inductions?

A. I performed inductions when I was a faculty member at Tufts New England Medical Center and at the University of Massachusetts Medical Center. It was a period of about 12 years.

Q. Have you ever conducted clinical research in the area of abortion?

A. Yes, I have.

Q. Have you ever designed or conducted a randomized trial?

A. Yes, I have.

Q. And did that involve abortion?

A. No, I conducted a randomized trial that compared methods of induction at term.

Q. And do you currently teach abortion methods?

A. I do.

Q. To whom do you currently teach abortion methods?

A. I teach abortion methods to the family practice residents that I referred to earlier. That is primarily early abortion methods. Also teach early medical abortion methods to the advanced practice clinicians who work at Golden Gate.

I sometimes teach second-trimester D&E methods to the physicians who work at Planned Parenthood Golden Gate.

[11]

I have a history of giving lectures in the medical schools in which I worked, and those involved abortions.

Q. And when you refer to teaching abortion methods to residents, are those residents of UCSF?

A. Yes, the residents—we do teach the residents at UCSF.

We also teach residents who are in other residency programs throughout the bay area. And they come over to Planned Parenthood Golden Gate to train in early surgical abortion methods.

Q. And, Dr. Paul, am I correct that you are the editor-in-chief of the recent text on abortion?

A. Yes.

Q. And what is that text?

A. It's called a Clinician's Guide to Medical and Surgical Abortion.

Q. And in addition to being the editor-in-chief of that text, did you author or co-author any of the chapters in that book?

A. Yes, I did.

Q. When was that—when was that book published?

A. 1999.

Q. Can you describe what your role was as editor-in-chief of that text?

A. Yes. As editor-in-chief I was responsible for overseeing the process of production of the book, and I was the primary contact with the publisher. I also was the primary person to [12] coordinate the work of the other editors.

I did work directly with some of the authors. I reviewed all of the chapters of the book, and exercised editorial authority over those chapters.

Q. And do you know what the reputation of this text is in the medical community?

A. I believe it's the standard reference text on abortion care.

Q. In addition to the Clinician's Guide text, do you have other publications in the area of abortion?

A. Yes. I have several publications in the peer review literature.

Q. Are those outlined on your curriculum vitae?

A. They are.

Q. Dr. Paul, in addition to being a board certified Ob/Gyn, you have a master's in public health with a concentration in epidemiology; is that correct?

A. Yes.

Q. What is epidemiology?

A. Epidemiology is the study of the distribution and determinants of health-related conditions in the popula-

tion. Simply put, it's applying research methods to determine who gets health-related conditions and why.

Q. And what role does epidemiology play in your work?

A. I apply epidemiologic methods when I do research. I also [13] have done peer reviews of articles, manuscripts that are submitted by authors to major medical journals. And one thing we have to do is determine whether the epidemiologic methods that are used are appropriate for the topic of the manuscripts.

Q. Have you ever taught epidemiology?

A. I helped to teach a reproductive epidemiology course at the BU School of Public Health.

Q. What is "BU"?

A. I'm sorry, Boston University.

Q. Dr. Paul, have you ever testified before as an expert witness in a case challenging a law that restricts abortion practice or restricts access to abortion?

A. No.

MS. GARTNER: Your honor, plaintiffs would move to qualify Dr. Maureen Paul as an expert in obstetrics and gynecology, all facets of abortion care, and epidemiology.

THE COURT: Any objection?

MR. QUINLIVAN: No objection.

THE COURT: Do you wish to voir dire the witness at this time?

MR. QUINLIVAN: Not at this time, your honor.

THE COURT: All right. She will be accepted as qualified.

MS. GARTNER: Thank you, your honor.

[14]

BY MS. GARTNER:

Q. Dr. Paul, I would like to ask you some background questions about pregnancy. What is the average length of a full term pregnancy?

A. Forty weeks.

Q. And how is the gestational age of the fetus calculated?

A. In two ways. The gestational age can be calculated from the first day of the last menstrual period, which is sometimes referred to as LMP. Or an ultrasound can be used, also, to date the pregnancy.

Q. If ultrasound is used to date the pregnancy, do you still refer to the gestational age in terms of LMP?

A. It is common, no matter which way you date the pregnancy, to say, for instance, that a woman is eight weeks LMP.

Q. Can you tell me when the first-trimester of pregnancy ends?

A. The total duration of pregnancy is 40 weeks, and pregnancy is divided into three trimesters of equal duration. So the first-trimester ends at about 13 or 14 weeks.

Q. And when does the second-trimester end?

A. About 27 weeks.

Q. Dr. Paul, what do you under the word "viability" to mean?

A. I understand the word "viability" to mean that the fetus has a realistic chance of long-term survival outside the uterus.

Q. And based on the available data, can you tell me when, in [15] your opinion, a normally-developed fetus is likely to become viable?

A. About 24 weeks.

Q. And is that LMP?

A. Yes.

Q. And throughout your testimony, when you refer to the number of weeks, are you referring to that number of weeks LMP?

A. Yes.

THE COURT: Could I ask a question? Is LMP the first day or last day of the menstrual period?

THE WITNESS: The first day of the last menstrual period, your honor.

BY MS. GARTNER:

Q. Dr. Paul, does pregnancy ever cause serious medical conditions for the pregnant woman?

A. Yes.

Q. Can you give me some examples of those?

A. Yes. There are conditions that are specific to pregnancy. One example is a condition called "preeclampsia," which is a condition that affects many of the systems of the body. It presents as high-blood pressure, and protein in the urine. But it can also include abnormalities of the liver, abnormalities of the blood-clotting system.

And it can progress to seizures, in which case the condition is called "eclampsia." There are infections that are [16] specific to pregnancy like chorioamnionitis, which is an infection of the uterus that occurs only during pregnancy.

And then there are conditions that can happen in nonpregnant women, but are more likely to happen in pregnant women. And an example of that would be the propensity to have blood clots, either in the lower extremities or in the lungs.

And that is called thromboembolism and pulmonary embolus.

Q. These conditions, these examples you have given of preeclampsia, chorioamnionitis and the blood clots, when in pregnancy are these conditions likely to occur?

A. Preeclampsia and chorioamnionitis are more likely to occur in the second and third-trimester. Blood clots can occur any time.

Q. And what about in women that are already unhealthy in some respect, can pregnancy ever make their underlying medical conditions worse?

A. Absolutely.

Q. Can you give me some examples of that?

A. Yes. Pregnancy entails many changes that happen in the body that can be tolerated by normal women, who are normal and healthy, but can be very taxing to women who have underlying medical conditions.

An example might be heart conditions. For instance, the blood volume in pregnancy nearly doubles. The heart rate goes up.

[17]

Q. Let me just stop you there. You are talking about the blood volume of the pregnant woman?

A. The blood volume of the pregnant woman, that's right. The amount of blood in the system nearly doubles during pregnancy, and the heart rate goes up. The amount of blood that is coming through the heart and that has to go out to feed the tissues is therefore greater. And the heart is working harder. So that if you have a woman who has a heart condition, this can be very taxing.

It can cause increased pressures in the heart that can backup into the lungs and you can get things called "pulmonary edema," that is fluid in the lungs or heart failure.

Another example would be diabetes. There are hormonal changes that happen in pregnancy that can make it very difficult to control the blood sugars in a diabetic so that you can get dangerously low blood sugars leading to seizures, or you can get dangerously high blood sugars, which can result in coma. So those are a couple of examples.

Q. Is there a particular time in pregnancy when such underlying medical conditions tend to worsen?

A. They tend to worsen as pregnancy progresses.

Q. And, Dr. Paul, have you treated patients in your medical practice with all of the types of conditions that we've just discussed who have chosen to end their pregnancies because of those conditions?

[18]

A. Yes, and others.

Q. Have you treated patients who have chosen to end their pregnancy because the fetus is diagnosed as having a serious anomaly?

A. Yes.

Q. Can you give me some examples of those from your medical practice?

A. Basically two types: one is chromosomal anomalies.

Q. Why don't you tell us what is a chromosomal anomaly?

A. The chromosomes are basically packages of genetic material, so it is genetic types of defects. You can have too many chromosomes, too few chromosomes or chromosomes that have structural defects. And I have treated women who have had all of those types of chromosomal anomalies.

The other thing is just anomalies of the fetus that are structural anomalies so that they are visible birth defects.

Q. Can you give me one or two examples of those?

A. Heart defects, or there is a neural tube defects that are defects of the spinal cord or brain.

Q. Have you treated patients with those sorts of fetal anomalies that have chosen to end their pregnancies?

A. Yes.

Q. And at what gestational ages are abortions for fetal anomalies generally performed?

[19]

A. Generally after the first-trimester.

Q. And why is that?

A. Because we often can't diagnose these anomalies until after the first-trimester. There may be abnormalities that appear on an ultrasound that just don't appear until the second or third-trimester, and that is when we first attack the anomaly.

And there is also genetic tests that can only be done in second-trimester.

Q. Dr. Paul, can you just describe briefly what is "ultrasound"?

A. "Ultrasound" is using sound waves in order to visualize the pregnancy.

Q. And is there a general time in pregnancy when women routinely have an ultrasound?

A. It is very common for women to have ultrasound during pregnancy, and most commonly in the second-trimester, maybe 13 to 20 weeks. If there is any question about dating, it could occur earlier, or there could be a second ultrasound or even a third ultrasound that is done.

The earlier in a pregnancy that you do the ultrasound, the better it is for the dating purposes. But you really need to do it a little bit later in the second-trimester if you are going to look for anomalies and things like that.

Q. When you say "dating," you mean to determine the gestational age of the fetus; is that right?

[20]

A. That's right.

Q. And what sorts of anomalies can be detected with ultrasound?

A. With ultrasound we can detect some apparent birth defects. So things like anencephaly, which is the absence of the brain.

The ultrasound is very good at detecting that. Things like abnormalities of the kidneys or the heart, it's not a hundred percent accurate, but it will pick up abnormalities like that.

Q. Now, what about the chromosomal anomalies that you were describing, how are those detected?

A. Those are detected through amniocentesis or chorionic villus sampling.

Q. And what is amniocentesis?

A. Amniocentesis is a method of obtaining a sample of amniotic fluid from the pregnancy sac by inserting a needle through the abdomen into the amniotic sac.

Q. And do pregnant women routinely have amniocentesis?

A. Not all pregnant women, no.

Q. Why is that?

A. Because it does carry some risks, so it tends to happen only—it tends to be recommended only in women who have risk factors for fetal anomalies. The incidence of fetal anomalies in general population is low, so it is not—it's not indicated to do amniocentesis on all women.

Q. So under what circumstances do the benefits of the [21] amniocentesis generally outweigh the risks of doing it?

A. The benefits outweigh the risk when a woman, pregnant woman has risk factors for a fetal anomaly. It may occur, for instance, if the woman is a little bit older

in age. Older women have increased risk for certain birth defects.

Another example would be if a woman had a family history of a particular type of genetic defect, then it would be indicated in that situation.

There are also situations where the ultrasound won't show a defect, a birth defect, but it will show things like too much amniotic fluid or too little amniotic fluid, and you worry that that may be an indicator of a chromosomal abnormality, so you would do amniocentesis in that case.

Q. What is the typical gestational age at which amniocentesis is performed?

A. Sixteen to 18 weeks. Although, it may be performed later if one of those ultrasound indicators like the too much fluid, too little fluid occurs, because I have seen ultrasound—amniocentesis done in the third-trimester if there is a suspicion by ultrasound that there may be a genetic defect associated with those ultrasound findings.

Q. How long does it take for the results of amniocentesis to come back, on average?

A. Minimum seven days. It can take two to three weeks.

Q. So Dr. Paul, you have testified that some maternal [22] conditions tend to worsen as pregnancy progresses, and other conditions don't develop until the second-trimester. And you have also testified that many anomalies can't be detected until the second-trimester. Does this mean that abortions for maternal or fetal indications are more likely after the first-trimester of pregnancy?

MR. QUINLIVAN: Objection, your honor, leading.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MS. GARTNER:

Q. Dr. Paul, do you have an opinion on the relative safety of carrying a pregnancy to term and through childbirth versus having an abortion?

A. Yes, I do. I—of course, many women carry pregnancies to term, and I have been part of their lives in these very joyous times. And I—so most women who are healthy do very well.

But, if you look just at safety data, then carrying a pregnancy to term is more risky than having an abortion.

Q. I would like to break that opinion down a little bit to understand your basis for concluding that. I would like to start first by talking generally about the safety of carrying a pregnancy to term and through childbirth.

In your work, Dr. Paul, do you regularly review data on the safety of pregnancy?

A. Yes, I do.

[23]

Q. And from what sources are the data that you regularly review?

A. The Centers for Disease Control and Prevention, or the CDC, publish data on pregnancy mortality. And there is also data on complications of pregnancy that result in hospitalization.

Also the journals are full of articles about specific conditions that can occur during pregnancy.

Q. When you review safety data, what sort of adverse occurrences do you look at?

A. Both morbidity and mortality.

Q. And what is the difference between morbidity and mortality?

A. Mortality relates to death, and morbidity relates to complications.

Q. And based on your knowledge of the literature in this area, what is your opinion about the overall safety of carrying a pregnancy to term in terms of mortality?

A. Carrying a pregnancy to term does carry a risk of death, albeit small. The current pregnancy-related mortality rate in the United States is about seven to eight per 100,000 live births. However, that rate is increased for certain groups of women, like older women, African-American women.

Q. And based on your knowledge of the literature in this area, what is your opinion about the overall safety of carrying a pregnancy to term in terms of the morbidity?

A. There are data that look at hospitalizations during [24] pregnancy as an indicator of pregnancy complications. And the data show—the most recent data show that there are about 12 hospitalizations for obstetrical complications per 100 deliveries. So it is quite a high rate.

Q. So does that mean that 12 percent of women that carry pregnancies to term are hospitalized before they give birth?

A. The denominator is deliveries, not women. So it is a little bit complicated. That is a simplified way of putting it, yes.

It really says that every 100 deliveries that occur, 12 will have admissions before the delivery that are due to pregnancy complications.

Q. And does the safety of carrying a pregnancy to term vary based on maternal age?

A. Yes, it does. In fact, the data—most recent data show that at—in terms of mortality—that at 35 to 39 years old, the risk of dying is about twice that of women who are less than 20 years old. And at age 40 and above, the risk is about five times.

Q. Five times?

A. The risk at less than 20 years old.

Q. Okay. Dr. Paul, can you give us an historical perspective on the safety of carrying a pregnancy to term, including childbirth in this country?

A. Yes. The pregnancy-related death rates have decreased [25] substantially. For example, there were about 850 per 100,000 live births in 1900, and there are seven to eight per 100,000 live births today.

Q. And when you are saying 850 or seven to eight, are those deaths due to pregnancy?

A. Yes.

Q. What is it that has happened to make pregnancy safer in this country?

A. I am not sure it is pregnancy being safer so much as our ability to treat the conditions of pregnancy has improved.

Q. Dr. Paul, I now would like to ask you a little bit about the safety of abortion, generally. Do you review data on the safety of abortion as part of your work?

A. Yes, I do.

Q. And, again, as with pregnancy, do you review both morbidity and mortality data?

A. Yes.

Q. What do you consider to be the most reliable sources for data on abortion-related morbidity?

A. Studies that were conducted by the Centers for Disease Control and Prevention in the 1970's. It was a program called "The Joint Program for the Study of Abortion," or JPSA.

Q. And how were the JPSA studies conducted?

A. The JPSA studies were large, very large, and collectively the JPSA studies included perhaps a quarter of a million. And [26] they were prospective, multi-centered studies, so that they involved numerous hospitals and clinics throughout the United States. And their purpose was to look at complications associated with legal abortion in the United States.

Q. When you say these studies were "prospective," can you explain what you mean by that?

A. Yes, they can be prospective, looking forward in time or in retrospective where the events occurred in the past, and you look backwards to determine if there is any associations between certain conditions and diseases or—certain risk factors and health conditions that you are looking at.

So these were prospective studies, which are generally considered to be better than retrospective studies.

They involved training people at the hospitals to keep track of women from the time that they had their abortion forward, looking forward to whether complications occurred.

Q. And you might have said this, but when were the JPSA studies conducted?

A. From 1971 to 1979.

Q. And who were the lead investigators of the JPSA studies?

A. Dr. Willard Cate directed the program, and Dr. David Grimes was the co-director.

Q And is Dr. David Grimes a co-editor of the text that you were the chief editor of on abortion?

A. Yes.

[27]

Q. And did JPSA publish the results of its studies?

A. Yes, in several articles.

Q. And is there a particular article or source that summarizes the conclusions of the JPSA studies on abortion-related morbidity?

A. There's a few. The one that I like is by Nancy Binkin (Phonetic).

MS. GARTNER: Your Honor, may I approach the witness to hand her this article?

BY MS. GARTNER:

Q. Dr. Paul, I have handed you what is Learned Treatise number 15.

Is this the article that you were referring to?

A. Yes, it is.

Q. And for the record, can you tell me the name of the article, the author, the publication and the date of publication, please?

A. The name of the article is "Trends in Induced Legal Abortion Morbidity and Mortality." The author is Nancy Binkin.

And this was published in "Clinics in Obstetrics and Gynecology" in 1986.

Q. Thank you. I would like to direct your attention, Dr. Paul, to page 8, table 7 of this article.

A. I don't have a page 8.

Q. Oh, I am sorry. I believe it is the last page of the [28] article.

A. Table 7, yes.

Q. Do you see table 7?

A. I do.

Q. Okay, good.

Dr. Paul, does this table summarize the JPSA findings on abortion-related morbidity?

A. Yes.

MS. GARTNER: We are attempting—what always seems to fail is the technology to put this up on the screen.

Your Honor, we have a technology person.

THE COURT: Certainly.

(Pause in the proceedings.)

THE COURT: While he is doing that, generally we don't publish the exhibits until they have been admitted into evidence. As I understand it, both sides have learned treatises they are going to use with their experts but are not going to move them into evidence; is that correct?

MR. QUINLIVAN: That's correct.

MS. GARTNER: That's correct.

THE COURT: So I am assuming there is no objection to the projection, even though—of these items, even though they are not going to be admitted?

MR. QUINLIVAN: No objection to the projection, but we will have an objection if it is being moved into evidence. [29] But we don't have an objection as to the projection.

MS. GARTNER: Yes, and we don't plan to move it into evidence, your honor.

THE COURT: All right.

BY MS. GARTNER:

Q. Dr. Paul, referring specifically to this table, can you tell me—along the top it says "JPSA I, JPSA II and JPSA III," with roman numerals. Can you tell me what the difference is between JPSA I, JPSA II and JPSA III?

A. They were three phases of the JPSA studies. The time intervals, which you can see, at which they were done were different. They also involved different subjects, different women and different institutions.

Q. Okay. What does this table tell you about the JPSA findings with respect to abortion-related morbidity?

A. May I use the pointer?

Q. Yes.

THE COURT: Yes.

THE WITNESS: Thank you.

You see the table is entitled: "Major Complication Rates per 100 Procedures Based on JPSA Studies."

Here it shows the type of procedure in the left-hand column, and the rates in the rest of the columns. So, what it shows is that for first-trimester suction curettage, which is another name for vacuum aspiration, the rates were about 0.2 to [30] 0.6 per—and that is a percent. So 0.2 to 0.6 percent. For induction methods that were used at the time, which saline instillation, and this is called prostaglandin instillation, the rates ranged from 1.7 percent to 3 percent.

And for D&E abortion, the rates ranged from 0.6 percent to 0.9 percent.

BY MS. GARTNER:

Q. And, again, when you say "the rates," that is the rate of major complications; is that correct?

A. That's right.

Q. And in the JPSA studies, what was considered to be a major complication of abortion?

A. JPSA collected data on 15 different serious types of complications, but most of them fell into three different major complications. And they are shown

down here: a fever that is sustained for three or more days; hemorrhage requiring transfusion; and unintended major surgery: abdominal surgery, hysterectomy, major surgery.

Q. And did the JPSA studies consider retained placenta to be a complication of abortion?

A. Yes, but not a serious one.

Q. And, Dr. Paul, are the abortion methods that were assessed in the JPSA studies the same ones that are used today?

A. There are significant differences.

Q. How were the D&E methods used today different than the ones [31] that were used at the time of the JPSA studies?

A. The main difference is in the way we dilate the cervix.

Q. And how are the induction methods used today different than the methods that were used at the time of the JPSA studies?

A. We use different types of medications and different groups of administration.

Q. Given the differences in how abortions are done today, in your opinion is it valid to rely on the JPSA studies in assessing abortion-related morbidity?

A. I think it is because JPSA established the Foundation for Abortion Safety. It is the largest data set available on complication rates from legal abortion in the United States.

There is just nothing that rivals it.

Q. In your opinion, is there a difference in the abortion-related morbidity today than there was at the time of the JPSA studies?

A. I can only speculate, but because our methods have improved I would assume that abortion safety has also improved for all methods.

Q. Does JPSA still exist as part of the CDC?

A. No.

Q. Why does it no longer exist?

A. It was discontinued because the question that it had been designed to answer about abortion safety after legalization of abortion had been answered. It showed unequivocally that [32] abortion was a safe procedure.

Q. And are there any additional recent studies looking at abortion-related morbidity?

A. Yes, there are articles in journals that mostly are single—come from a single institution, and they are smaller, but they generally confirm the safety of abortion.

Q. And, Dr. Paul, what do you consider to be the most reliable data on abortion-related mortality?

A. The CDC data.

Q. And is that data different from the JPSA CDC data?

A. Yes. The CDC has an accurate surveillance program for identifying deaths related to both pregnancy and abortion.

MS. GARTNER: Your honor, may I approach the witness to hand her another article?

THE COURT: Yes.

MS. GARTNER: Thank you.

BY MS. GARTNER:

Q. Dr. Paul, I am handing you what is Exhibit 63. Can you tell me, Dr. Paul, what this document is?

A. This is an article that summarizes the information on abortion mortality collected by the CDC from 1972 to 1987.

Q. And is this article prepared by CDC personnel?

A. Yes, it is.

Q. And is it based on data collected by the CDC?

A. Yes, it is.

[33]

MS. GARTNER: Your honor, we would move to introduce this Exhibit 63 into evidence under the public records and vital statistics exceptions to the hearsay rule, which are Federal Rules of Evidence 8038 and 8039.

THE COURT: Any objection?

MR. QUINLIVAN: Just a moment, your honor.

Your Honor, we do have an objection. My understanding is that this was not published by CDC. If it was published by CDC, we would not have an objection. If that is clarified, I'll withdraw the objection. But my understanding is that this paper was not published by the CDC.

THE COURT: All right.

MS. GARTNER: Your honor, I think that is correct, that it was published in the journal, "American

Journal of Obstetrics and Gynecology." However, the exception states that the documents that are exceptions to the hearsay rule include—and I am reading now from 8038:

"Records, reports, statements or data compilations in any form of public offices or agencies setting forth the activities of the office or agency."

And it goes on. So it does say "in any form," and Dr. Paul has testified the authors of this article are all employees of the CDC. And the data reported in this study is all data that was collected by the CDC as a public agency. So we would say this falls within the exception.

[34]

THE COURT: All right. And you became aware of this particular item through the journal, as it was published in the journal?

THE WITNESS: Yes, I did.

THE COURT: All right. Anything else on the matter?

MR. QUINLIVAN: Nothing more on this.

THE COURT: I think it is not precluded by section 8 and it clearly isn't by section 9, so I will permit it.

MS. GARTNER: Thank you, your honor.

THE CLERK: Sixty-three into evidence.

(Plaintiff's Exhibit 63 was received in evidence.)

BY MS. GARTNER:

Q. Dr. Paul, is the data contained in this article the sort of data that you regularly review in your work?

A. Yes.

Q. And how is the data in this publication compiled?

A. The CDC, as I testified earlier, has an active surveillance system to identify abortion-related deaths. That means that it goes to great lengths to identify deaths and uses several sources to do that, including vital records, death certificates of the states, medical examiner reports, health care providers, media reports.

There is about 10 different sources that they use to ascertain the deaths.

[35]

Q. Dr. Paul, just for shorthand, can we refer to this publication as Lawson, or the Lawson publication?

A. Lawson is the first author, yes, so that is fine.

Q. Dr. Paul; I would like to direct your attention to table III, roman numeral III of this article which appears on page 1368, which is also the table that is—that appears on the screen.

Can you summarize what this table tells us about the risk of death from abortion in the time period covered by this article from 1972 to 1987?

A. Again, if I can use my pointer.

The table is case fatality rates, which is the same as death rates, which is the number of legal induced abortion deaths per 100,000 legal induced abortions.

And I do want to clarify that "induced" is being used in a very generic way here. It is not referring just to induction abortion. "Induced abortion" is a very generic term that is used sometimes for all methods of abortion.

So it is the case fatality rates for legal induced abortion by type of procedure and length of gestation, United States, 1972 through '87. And across here is the different gestational ages. And these are the types of procedures.

But in order to summarize, I would direct attention to this figure of one, which is the overall death rate from all methods of abortion. It is one per 100,000 procedures. So it [36] is very low.

And the other thing in general that you notice is that the death rate increases as gestational age increases.

Q. Are you looking for that at the bottom line, the total?

A. The total, yes. So these are the—this is the total death rate from—at eight wee' or less, from all types of procedures that are done at that gestational age.

And the death rate is 0.4 for 100,000. Whereas, if you look at 21 weeks or greater, again, the rate is 10 per 100,000 procedures.

Q. Does the Lawson article tell us whether the risk of death from abortion has changed in the period since abortion was legalized nationwide in 1973?

A. It's not reflected on this table, but the article tells us, yes, that the risk of death has decreased over 90 percent, from about four per 100,000 in 1972, to about 0.4 in 1987.

Q. Dr. Paul, earlier when you were discussing the safety of carrying a pregnancy to term and through childbirth, you said that as women get older the risk for carrying a pregnancy to term increases; is that correct?

A. That's right.

Q. Is the same thing true for abortion?

A. No.

Q. Is that reflected in the Lawson article?

A. When they looked at the most recent period of 1983, 1987, [37] there was—which is our most recent data—there were—there was no association between the age of a woman and her risk of death from abortion.

Q. And then, Dr. Paul, to summarize all of your testimony about abortion-related morbidity and mortality, what is your opinion on the overall safety of abortion?

A. That it is very safe.

Q. Now, you've just been testifying about the overall safety of pregnancy through childbirth and the overall safety of abortion. Based on the various data you have been testifying about, what overall conclusions do you draw about the relative safety of abortion and pregnancy continued through childbirth?

A. The conclusion I draw is that overall abortion is safer than carrying a pregnancy to term and going through childbirth.

And that's based on both mortality data over all the risk of childbirth—of death from childbirth is about 10 times that the risk of having an abortion.

And if you look at second-trimester, that under 16 weeks gestation that the risk of having an abortion is clearly less than the risk of carrying a pregnancy to term.

At 16 weeks gestation and higher, the rates are about the same. But for older women, the rates of

dying from pregnancy and childbirth are higher than the risk of having an abortion. I would say that includes in the second-trimester.

And then,-in terms of complication rates, the data [38] that I talked about in terms of hospitalization show that it's very common to have complications occur during pregnancy. And that when you look at that morbidity data that, in my opinion, hands down abortion is a safer option than carrying to term.

Q. Thank you.

Now, Dr. Paul, I would like to ask you some questions about how often abortions are performed and at what gestational ages they tend to be performed. Are there agencies that collect and compile data about abortion?

A. Yes.

Q. What are those agencies?

A. The Centers for Disease Control and Prevention, and the Alan Guttmacher Institute.

Q. What is the Alan Guttmacher Institute?

A. It's a private, independent research institute based in New York City.

Q. Can I refer to that as AGI? Will you know what I am referring to?

A. Sure.

Q. Which of these organizations, CDC or AGI, is generally understood as having the most complete data on the numbers of abortions performed in this country overall?

A. The AGI. The CDC even acknowledges that the AGI has the better data on that particular aspect of abortion.

Q. And what is the most current year for which AGI has data on [39] the number of abortions in this country?

A. In the year 2000.

Q. And according to that data, how many abortions were performed in this country in the year 2000?

A. About 1.3 million.

Q. And do either the CDC or AGI collect data showing the frequency of abortions at particular gestational ages?

A. Yes, the CDC does.

Q. Where is that published by the CDC?

A. In a publication called "Morbidity and Mortality Weekly Report," or MMWR.

MS. GARTNER: Your honor, may I approach the witness?

BY MS. GARTNER:

Q. I am handing you Exhibit 7, Dr. Paul. Dr. Paul, is this the document that you were referring to a moment ago?

A. Yes, it is.

Q. And for the record, can you state the full name of this document?

A. It's entitled: "Abortion Surveillance-United States, 2000." And it's the "Morbidity and Mortality Weekly Report" of November 28th, 2003.

Q. And does the CDC publish "Morbidity and Mortality Weekly Reports" on other things, in addition to abortion?

[40]

A. Oh, yes, on many conditions, pregnancy-related and not pregnancy-related.

Q. And do you routinely review the MMWR as part of your work?

A. Yes, I have an online subscription.

Q. And as far as you know, is this the most current MMWR related to abortion?

A. Yes, it is.

Q. And how does the CDC compile the data in this report?

A. From state health departments and the health departments of New York City and the District of Columbia.

MS. GARTNER: Your honor, we would move to introduce Exhibit 7 into evidence again, under the public records and reports and vital statistics exceptions to the hearsay rule.

THE COURT: And does the government continue its objection?

MR. QUINLIVAN: Given that it is published by the CDC, we don't have an objection, your honor.

THE COURT: Thank you. Admitted.

THE CLERK: Seven into evidence.

(Plaintiff's Exhibit 7 was received in evidence.)

BY MS. GARTNER:

Q. Dr. Paul, I would like to direct your attention to page 16, table 1 of this exhibit, which Ms. Parker is also putting up on the screen. [41] Dr. Paul, is this the table in this document, the MMWR document, where the frequency of abortions at different gestational ages is discussed?

A. Yes.

Q. Can you tell us generally what information is contained in this table?

A. Yes. The table is called "Characteristics of Women Who Obtained Legal Abortions, United States." Challenged in seeing that far 1973 to 2000.

It's part of a larger table. What this is is the information on the gestational ages at which abortions are done.

So, on the left here you have the weeks of pregnancy, the weeks of gestation divided into different intervals. And these are the different years for which the data is collected. And this is the column for the year 2000, which is the most recent year.

Q. Okay. And in general, what does this table tell us about the gestational ages at which abortions are performed?

A. That most of them are performed in the first-trimester.

Q. And specifically, what does this table tell us about the percentage of abortions that were performed prior to 13 weeks LMP in the year 2000?

A. You have to do a little adding of the columns here. But if you add up the figures here for less than 13 weeks, you get [42] about 88 percent.

Q. And what does this table tell us about the percentage of abortions that were performed between 13 and 15 weeks in the year 2000?

A. You can see that directly on the table, that about 6.2 percent of abortions were performed between 13 and 15 weeks gestation.

Q. And what percentage of abortions were done between 16 and 20 weeks gestation?

A. 4.3 percent.

Q. And what percentage of abortions were done after 20 weeks in the year 2000?

A. 1.4 percent.

Q. So I am going to challenge your math abilities a little more, Dr. Paul. You previously testified that there are approximately 1.3 million abortions in this country in the year 2000; is that right?

A. Yes.

Q. So looking at table 1, out of the 1.3 million total abortions, approximately how many were performed in the year 2000 after 16 weeks LMP?

A. Approximately 74,000.

Q. And after 20 weeks LMP?

A. Approximately 18,000.

Q. Dr. Paul, what I would like to do now is to give the court [43] an overview of the different methods of abortions that are available for women to choose from. First of all, what are some of the factors that determine what methods of abortion are available to a woman to choose from?

A. The gestational age of the pregnancy is probably the biggest, but also the availability of a trained provider for the particular methods.

Q. And are all abortion methods generally available throughout the United States?

A. No. There is a shortage of providers in the United States such that about 87 percent of counties in the United States have no abortion provider. Where there is an abortion provider it is more likely that the provider is trained in first-trimester abortions instead of the later abortions.

And where there is a second-trimester provider, it is more likely that the physician is trained in induction abortion rather than D&E.

Q. Dr. Paul, you said that gestational age is the most important determinant of what methods are available to a woman.

So I want to follow up on that. What methods of abortion are available to a woman in the first-trimester of pregnancy?

A. There's early medical abortion methods that basically involve giving medication to cause the pregnancy to stop growing and to be expelled from the uterus, and there is vacuum aspiration abortion.

[44]

Q. And can you describe briefly what vacuum aspiration abortion is?

A. It is using a source of suction to evacuate the uterus. It can be manual vacuum aspiration, just a syringe-like device that we use to create the suction, or it can be an electric pump that creates the suction.

Q. And what methods of abortion are available in the second-trimester of pregnancy?

A. D&E abortion, dilation and evacuation, which can occur either through disarticulation or as an intact procedure. And there is induction abortion, which is basically giving medications to cause labor contractions to have the woman expel the fetus.

Q. And, Dr. Paul, is there a particular term that you use to describe D&E's that occur by intact extraction?

A. I say the word "intact" D&E. I think it is really just a variant of D&E, so I wouldn't necessarily always identify them separately.

In the textbook when we have a section on it we refer to it as "intact D&E."

Q. And when you say "the textbook," are you referring to your "A Clinician's Guide to Medical and Surgical Abortion"?

A. Yes, I am.

Q. Dr. Paul, if you know, do some doctors use the term D&X to describe abortions in which the fetus is removed with intact [45] extraction?

A. I have seen that used in various ways. I mean, I have heard physicians use it generically to be pretty synonymous with intact D&E.

I do know that ACOG had a specific definition in a publication that it had described something that was much more specific, but I find that it is not really uniform the way that people use that term.

Q. Dr. Paul, when you say "ACOG," is that the American College of Obstetricians and Gynecologists?

A. Yes, it is.

Q. In your opinion, are intact D&E or D&X a distinct procedure from D&E ?

A. Not in my opinion. I consider them a variance of D&E.

Q. Dr. Paul, where are most—where are most D&E procedures performed?

A. In clinics.

Q. And is that an outpatient type setting?

A. Yes, a nonhospital-based outpatient clinic.

Q. And where are most induction abortions performed?

A. In hospitals.

Q. And why is that?

A. Well, induction abortion involves giving medications to put a woman into labor, which can happen over several hours, sometimes even takes a day or two. So—and there are some [46] side effects that occur. So in order to be able to give the woman the medications to induce the labor in addition to give her medications to help with the pain that she may be having during the contractions and to treat side effects that can occur, like nausea, vomiting or fever, monitoring in a hospital is important over that extended period of time. And clinics are not set up to do that kind of longer term monitoring.

Q. Now, if for some medical reason a woman who was having a second-trimester abortion couldn't have either a D&E or an induction procedure, are there other abortion methods that are available to her?

A. There is hysterotomy or hysterectomy. They are methods that are available, although the death rates from them, in my opinion, are prohibitively high.

Q. Can you just describe briefly what hysterotomy and hysterectomy are?

A. A hysterotomy is removal of the pregnancy through an incision in the uterus, and so you do an abdominal incision to get to the uterus, and then another incision in the uterus to remove the pregnancy.

And hysterectomy is removal of the entire uterus, in which case the pregnancy is also removed.

Q. And are those, hysterotomy and hysterectomy, are those commonly performed in this country?

A. No, they are very uncommon, thank goodness. Overall, they [47] are about 0.01 percent of all abortions and about 0.07 percent of second-trimester abortions.

Q. Dr. Paul, are there data showing what percentage of abortions are performed by each available method at particular gestational ages?

A. Yes.

Q. And who collects that data?

A. The CDC.

Q. And is that part of the CDC abortion surveillance document that we were just looking at?

A. Yes, it is.

Q. Dr. Paul, if you would like to turn back to Exhibit 7, which you should have there still to page 32.

Is table 18 on page 32 the data that you are referring to?

A. Yes.

Q. Can you explain the information that is contained in this table, please?

A. Yes. Title is "Reported Legal Abortions by Known Weeks of Gestation and Type of Procedure."

And on the left-hand column here is the type of procedure. Across the rows we have the gestational ages increasing from left to right. And then, the data is in the rest of the table.

Q. And what is meant on this table? I'm looking at the [48] left-hand column, it says:

"Intrauterine saline instillation, intrauterine prostaglandin instillation and medical."

What procedure do those refer to?

A. Those are different methods of induction abortion that were used at the time.

Q. And that all three of those are induction abortions?

A. Yes, they are.

Q. And where—

A. Although, I—yes, that's right. There is a footnote in this table that indicates that "medical" involves primarily the use of vaginal prostaglandins, which is a method for use to induce an induction abortion.

Q. And where in this table are data for D&E reflected?

A. Under "curettage." So the D&E's would be the curette abortions that were done at 13 weeks or greater. So, that's how the CDC categorizes them.

Q. And are data for intact D&E abortions reflected in this table?

A. Not separately. But as I said, intact D&E is a variant of D&E, so I strongly suspect that there are intact D&E's that are included in this—these data, as well as D&E's that proceed by disarticulation.

Q. Looking at these data for 16 to 20 weeks gestation, what percentage of abortions were done by D&E versus what percent [49] for inductions?

A. At 16 to 20 weeks gestation about 95 percent were done by D&E.

Q. Is that—I am sorry. Just to be clear. It is a little hard to read. Are you there pointing to the number of 94.6?

A. 94.6, yes. This 16 to 20; is that what you are asking?

Q. Yes.

A. So 94.6, which I am rounding off to 95 percent. About 95 percent were done by D&E abortion, and about 5 percent by induction.

Q. And then, looking at these data with respect to all abortions after 20 weeks gestation, the same question: what percentage of women had D&E versus what percent had induction abortions?

A. Those data are right here. About 85 percent had D&E abortion, and about 15 percent had induction abortion at 21 weeks or greater.

Q. Dr. Paul, we have gone through a lot of background information, but now I would like to focus in on the particular methods of abortion that would, in your opinion, be affected by the law at issue in this case.

So why don't we identify what those are? In your opinion, would any of the first-trimester methods that you described ever be affected by this law?

A. Not in my opinion.

[50]

Q. And in your opinion, would hysterotomy or hysterectomy abortions every be affected by this law?

A. No.

Q. In your opinion, would the D&E method ever be affected by this law?

A. Yes.

Q. And in your opinion, would the induction method ever be affected by this law?

A. It could be.

Q. Why don't we start by talking about the D&E abortions?

What I would like you to do is to explain in greater detail how you perform a D&E. And start with telling us in general what are the primary components involved in a D&E abortion?

A. There are two primary components. One is cervical preparation, and the other is evacuation of the uterus.

MS. GARTNER: Your honor, with your permission we have some charts or diagrams that may be helpful. Thank you.

Your honor, are those placed in a way that you can see it?

THE COURT: I can see it.

THE WITNESS: May I step down, your honor—

THE COURT: Sure.

THE WITNESS: —if I need to?

BY MS. GARTNER:

Q. Dr. Paul, what I would like you to do is explain to the [51] court why it is necessary to prepare the cervix for a D&E abortion. And if it is helpful to you, you know, feel free to use one of these diagrams.

A. I think I will use this diagram over here to illustrate that. This is the uterus (indicating). The uterus—as you can see, this is a nonpregnant uterus. It is a pear-shaped organ, and it has a narrowing that happens down here at the neck. That is called the cervix.

The cervix has some length. There is something called the external os, which is the external opening that's right at the top of the vagina.

And then, there is the internal os, which is at the other end of the cervix.

Q. And what is the distance, on average, between the internal os and the external os?

A. It certainly can vary, and especially during pregnancy. But it can be as much as 3 inches. It can be as little as 1 inch.

Q. And I am sorry to interrupt you. And then, what is it—if you can explain to us why the cervix needs to be prepared for the D&E abortion.

A. So the cervix is normally closed. It's the entrance into the uterus where the pregnancy is. And our goal in doing any abortion is to get something larger, which is the fetus, out of something smaller,

which is the cervix, without causing injury [52] to the cervix.

So in order to do that, it's necessary to prepare the cervix before you try to bring out the fetus. And that means to dilate the cervix, soften the cervix, get it ready, basically, for the evacuation.

Q. Thank you.

You mentioned two things: dilating the cervix and softening the cervix. What are the ways that you use to dilate the cervix?

A. I would say that there are ways that I use to prepare the cervix, because each method will do some dilation and some softening. So it is kind of a blurring of those, so I just want to be clear about what I am saying. And that is: what are the methods that I use to prepare the cervix?

One of them is the use of osmotic dilators, and the other is the use of medications to prepare the cervix.

Q. Thank you for that clarification. Why don't we talk first about the osmotic dilators. Can you explain what that term means?

A. An osmotic dilator is a short stick of compressed seaweed or synthetic material that is placed into the cervix. It absorbs fluid from the cervix and vagina, and expands, kind of like a dried piece of seaweed on the beach expands when it gets wet and gradually stretches the cervix open.

MS. GARTNER: Your honor, I have a laminaria. Would [53] you object if I handed it to Dr. Paul?

THE COURT: Sure.

BY MS. GARTNER:

Q. Dr. Paul, is that a laminaria?

A. Yes, it is.

THE COURT: Laminaria being what? May I see it?

THE WITNESS: So this is an example of a laminaria. It's one type of osmotic dilator. It is made of compressed seaweed.

BY MS. GARTNER:

Q. And do laminaria come in different sizes?

A. Yes.

Q. And what size is this one?

A. This is a large.

Q. And when you say—when you say "they come in different sizes," do they come in different lengths and different widths or—

A. Different widths.

Q. Can you describe how you insert the laminaria into the woman's cervix?

A. Yes. First I do an examination, get an idea of—just to be sure that things are fine in terms of the size of the uterus, the position of the uterus, where the cervix is located in relation to the vagina. I then insert a speculum, which is what we use when we do Pap smears and general gynecological [54] exams to visualize cervix, so it is a small instrument that we put into the vagina and open up, and the cervix comes into view.

I then wipe off the cervix with an antiseptic solution. And sometimes I will put a little numbing

medicine around the cervix to make the insertion more comfortable.

I then use an instrument to grasp the laminaria, and I put the laminaria into the canal. So I am putting it through that external os and up the canal and into that—just a little passed that internal os.

Q. And I think you may have said this, but what is it about the laminaria that causes dilation?

A. They absorb fluid and expand and stretch the uterus, the cervix open.

Q. And how many laminaria do you use?

A. As many as will comfortably fit without forcing.

Q. And does that number vary by the gestational age of the pregnancy?

A. Well, I have minimum criteria by gestational age. So that, you know, it is important, for instance, at 14 to 16 weeks gestation, I would want at least two large laminaria. At 16 to 17, a minimum of three. And then, at 17 to 18, six, a minimum of four. But I really want to emphasize the minimum, because in my opinion the more you can get comfortably in without forcing the better.

[55]

Q. Okay. And do you ever do a second insertion of laminaria for one patient?

A. Very rarely.

Q. And how long do you leave the laminaria in place before you begin the evacuation part of the procedure?

Q. It can vary, again, by gestational age, but generally at 16 weeks and over we leave the laminaria in overnight.

Q. And can you predict the amount of dilation you will achieve with the laminaria?

A. No.

Q. Why is that?

A. Because women cervixes just differ, and there is just great variability in the amount of dilation you can get in different women, given the same number of laminaria inserted.

Q. And how do you determine if the dilation that you've achieved is sufficient to continue with the procedure?

A. I need enough dilation to get the instruments in that I use and to have some extra mobility to be able to move those instruments.

So the instruments that I use on the gestational ages I do are 16 to 17 millimeters in diameter. So I am going to want, you know, 18 or more millimeters as a ballpark.

Q. In your opinion, in doing a D&E, is it possible to achieve too much cervical dilation?

A. Not in my opinion.

* * * * *

[57]

BY MS. GARTNER:

Q. Dr. Paul, I think I had just asked you whether in doing D&E abortions and preparing the cervix if it is

ever possible to achieve too much cervical dilation, in your opinion?

A. Not in my opinion.

Q. And why is that?

A. Because the more dilation that I have, the easier the evacuation is, and usually the faster, too.

Q. If dilation is so beneficial, why don't you routinely dilate more than you do now?

A. Well, I already said that I put in as many laminaria as I can that will comfortably fit without forcing. And that generally gives me the amount of dilation that I need to accomplish the abortion safely at the gestational ages that I do it.

If I am going to do more dilation, I would need to bring the patient back for a second set of dilator insertions, which would be—which would delay the abortion by 24 hours. And as you weigh kind of the factors it just doesn't make a lot of sense for the gestational ages that I do to do two sets of dilator insertions.

Q. And at what gestational age do you begin using overnight laminaria before the abortion?

A. Sixteen weeks.

[58]

Q. So, you said that osmotic dilation is one of the ways you prepare the cervix; is that right?

A. That's right.

Q. What are some of the other ways that you prepare the cervix for the evacuation?

A. The other main way is to use a medication called misoprostol?

Q. What is misoprostol?

A. It is a prostaglandin agent. And prostaglandin agents can cause some contractions, and they also affect the substance of the cervix in a way that softens it.

Q. I don't know if you can describe briefly how that works.

A. You mean, how—how it works?

Q. Yes.

A. Well, the cervix is made up of fibers called "collagen fibers" that are kind of cross-linked, and it affects the fibers in a way that makes the cervix softer. And it also causes contractions, of course, which helps to dilate and soften the cervix.

Q. And how is the misoprostol administered to the woman?

A. In various ways. It can be administered through the vagina, just placed into the—they are little white tablets that we place into the vagina. They can be swallowed. And they can be placed in the cheeks. That is called buccal administration, or under the tongue, which is sublingual [59] administration.

Q. And in your practice, how do you administer misoprostol?

A. Buccal administration.

Q. And just for the court reporter, could you spell "buccal," please?

A. B-U-C-C-A-L.

Q. And when in relation to the evacuation part of the procedure do you administer the misoprostol?

A. We generally administer it about 90 minutes before the abortion. There's a range. It can be 90 minutes to three hours.

Q. And do all women respond to cervical ripening with misoprostol in the same way?

A. No. Once again, there is a lot of variability in women's response to the cervical ripening.

Q. After you have given the woman the misoprostol, do you allow her to leave the health center?

A. No.

Q. Why is that?

A. Because women can get contractions and actually have a simultaneous abortion. They can actually miscarry, which we don't want to have happen at home. It has been reported in the literature if you use it the night before an abortion that women can actually expel a fetus at home, and we don't want that to happen.

[60]

Q. And, Dr. Paul, I think I should have asked you this before, but after you insert the laminaria when you are using laminaria in an overnight setting, after you have insertd [sic] the laminaria, can the woman leave the health center with the laminaria in place?

A. Yes. She can carry out her normal life.

Q. You said that the fetus, that the misoprostol can result in the fetus being expelled; is that correct?

A. That's correct.

Q. Does it sometimes happen that the fetus is completely expelled from the woman as a result of the misoprostol?

A. Yes, I have had that happen.

Q. Does it sometimes happen that the fetus is partially expelled from the uterus as a result of just the misoprostol?

MR. QUINLIVAN: Objection, leading, your honor.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MS. GARTNER:

Q. When that happens, when the fetus is partially expelled, could a part of the fetus past the navel be outside of the uterus?

MR. QUINLIVAN: Objection.

THE WITNESS: Absolutely.

MR. QUINLIVAN: Objection, leading.

THE COURT: Overruled.

[61]

BY MS. GARTNER:

Q. Could a part of the fetus past the navel be outside the woman's body as a result of the misoprostol?

A. Yes.

Q. Could it be alive when that happens?

A. Yes.

Q. In that situation where the fetus is partly expelled simply as a result of the administration of misoprostol, how would you complete the procedure in that circumstance?

A. Well, I would apply traction and pull on the fetus to see if the whole fetus would deliver without any other kind of intervention. If the head was lodged at the internal os and couldn't come through, then I would disarticulate the neck, and then complete the procedure with my forceps, going in to get the calvarium, which is the head of the fetus.

Q. Dr. Paul, for how long have you been using misoprostol for cervical ripening before doing D&E abortions?

A. About three years.

Q. At what gestational ages do you use it?

A. I use it by itself usually between 14 weeks and the beginning of the 16th week. Sixteen to 17 weeks I tend to use overnight laminaria. And then, at 17 weeks and up, I tend to combine the methods, using both laminaria and misoprostol.

Q. So from 16 to 17 weeks you would tend to use only the laminaria; is that right?

[62]

A. Yes, it is like 16—throughout the 16th week. And then, once 17 weeks comes, I tend to use both. It can vary a little bit, depending on if the woman had a lot of deliveries in the past in which case I am going to have to dilate a little easier with my method. So, but, in general, those are my—the protocols that I follow.

Q. Dr. Paul, I would like you now to describe in detail the evacuation part of the D&E procedure. When the woman returns to your health center after the laminaria has been in place overnight or if she has only had the misoprostol, if the misoprostol has been in place for the requisite time period, please describe in detail what you do up to the point where you are going to extract the fetus.

A. I do a pelvic examination again. If she has laminaria, and sometimes I can remove the laminaria during that examination just with my hands. Pelvic examination involves putting two fingers in the vagina, and the other hand on top of the woman's abdomen and kind of trying to assess, again, the size and position of the uterus, which is extremely important before you do a procedure. So, when I have my fingers in the vagina sometimes I can just extract the laminaria at that time.

Q. Let me interrupt you. Can you describe what you mean by "The position of the uterus"? [63] And if it helps, feel free to use that.

A. Can I use the diagram?

THE COURT: Yes.

THE WITNESS: I don't know where the pointer went. Anyway, this is a side view of the woman. So here you see this is the bladder from the side (indicating). This is the vagina (indicating). And this, again, all we have is a nonpregnant uterus in the diagram. This is the uterus, and this here is the cervix (indicating). These are the bowels back here (indicating). So as you can see, there is a natural angle that occurs between the vagina and the uterus. That changes somewhat, of course, as the uterus enlarges. But there is

also a natural angle between the cervical canal and the body, rest of the body of the uterus.

So before I do a procedure where I am going to insert instruments into the uterus, I need to know where the uterus is sitting. This shows the uterus is sitting towards the front of the woman's abdomen. But you can have uteruses that can sit in the middle or you can have the uterus kind of tipped towards the back.

Again, as the pregnancy grows, that can change a little bit. But I have had situations where even in the second-trimester the uterus remains tipped towards the back.

[64]

So it is very, very, very important to know the position of the uterus so you have an idea of which way to put your instruments in so as not to cause injury.

BY MS. GARTNER:

Q. And I am sorry. I interrupted you in midstream. I lost track of exactly what you were saying. I think you were talking about the pelvic exam that you do at the beginning.

A. If I can remove the laminaria at that time, then I do, if it is easy. I then administer pain medications that usually before a second-trimester abortion we will give pain medications and a sedative through an intravenous line. We don't put women all the way to sleep. It's called "conscious sedation." It helps women relax and also decreases the discomfort associated with the procedure. I then insert the speculum into the vagina and visualize the cervix. And I put a grasping instrument called a tenaculum on the cervix to stabilize it, and so

that I can move this sort of layer in the procedure. But I could put a tenaculum, usually, on the cervix.

And then I administer numbing medicine, the cervical anesthesia. And I use a small forcep to remove the laminaria, if they are in place.

Q. And, Dr. Paul, can you explain again why you use the tenaculum on the cervix? What do you do with the tenaculum?

A. There is a couple of things you can do. As you are pulling [65] out the laminaria, it holds the cervix still so that the whole uterus isn't moving with you as you are trying to get out the laminaria, right? And during the evacuation procedure especially I use it to draw the cervix as far down to me, towards me as possible, towards the opening of the vagina. So, I use it for mobility to be able to move the uterus around, move the cervix around during the evacuation procedure.

Q. Dr. Paul, before you do anything to move the cervix, what is an average length or an average distance from the opening of the cervix that's closest to the vaginal opening—to the vaginal opening?

A. It can really vary. It really—I really can't say that there is an average length. It may be sitting just a couple of inches up from the vaginal introitus. It may be four or five inches up. So it can vary.

Q. And you used the term "vaginal introitus." What is that?

A. The opening of the vagina.

Q. When you say that you use the tenaculum to pull on the cervix, how far can you bring the cervix down towards the vaginal introitus?

A. It varies, but frequently it is very close to the vaginal introitus.

Q. Do you try to avoid the circumstance where it comes close to the vaginal introitus?

[66]

A. No, I mean, I like when it comes close to the vaginal introitus. It allows me to see better, and to—it brings the cervix closer to me, so it makes it easier for me to insert my instruments. And the importance of it is that it helps to straighten out those angles so that you can get your instruments in easier.

Q. And when you say "those angles"—

A. The angles of the uterus that I was referring to when I was at the diagram.

Q. Dr. Paul, is there anything else you do before you actually begin the evacuation?

A. No. I have given the numbing medicine, given the medicine through the IV, clean off the cervix with an antiseptic solution.

Q. What is the first thing you do to evacuate the uterus?

A. I break the bag of water, either by just breaking it and allowing it to drain, the fluid to drain out, or using suction.

Q. And what is the bag of water?

A. It is the amniotic sac, is the technical term for it. It is the fluid in which—it is the sac in which the pregnancy is located.

Q. And I interrupted you. You were saying that sometimes you use suction to break the bag of waters?

A. Yes. Sometimes I will insert a suction cannula it's called [67] with a little tube attached to suction that breaks the bag and sucks out the fluid.

Q. And when you begin the evacuation, is the fetus ever alive?

A. Yes.

Q. How do you know that?

A. Because I do many of my procedures especially at 16 weeks under an ultrasound guidance, so I will see a heartbeat.

Q. Do you pay attention to that while you are doing the abortion?

A. Not particularly. I just notice it sometimes.

Q. So after you've broken the bag of waters and the fluid is either drained or you've suctioned out the fluid, what do you do next?

A. I evacuate the fetus.

Q. And can you describe how you do that?

A. Yes. I do it using an instrument called forceps. So I insert the forceps and grasp the fetus and pull. That's all the while putting traction on the tenaculum to straighten out that angle. And sometimes the fetus comes out in pieces, and I make instrument passes until the entire fetus is evacuated. And sometimes the whole fetus will come down into the vagina, at least as far as the head.

Q. Okay. Does it ever come out completely without the head becoming lodged?

[68]

A. Rarely it does.

Q. And, in general, what is your objective in evacuating the uterus?

A. My objective is to empty the uterus in the safest way possible.

Q. Is there any advantage to doing the evacuation quickly?

A. Yes, quickly and safely is best. But if you can do the procedure expeditiously, there are some advantages, the biggest being that you have less bleeding and shorter duration of discomfort for the woman.

Q. Why is there less bleeding if the procedure takes less time? Where is the bleeding coming from?

A. Well, if the placenta has detached at all, then there is blood vessels there that can bleed. And the key thing is that the uterus can't contract well to seal off blood vessels and stop bleeding until it is empty.

Q. Okay. Talking now about the situations where the fetus comes out in parts, how many instrumental passes does it typically take to empty the uterus?

A. There is no typical. It could be as many as—as little as two or three or as many as 10 to 15.

Q. And do you have a goal for how many passes it will take?

A. As few as possible.

Q. And why is that your goal?

A. Because every time you pass a forceps into the uterus, [69] there is a small risk of injury.

Q. And can you explain how that would happen?

A. Yes. You can get a laceration of the cervix or a perforation or laceration of the uterine wall with the instruments.

Q. And would that still be a possibility if you were doing the procedure under ultrasound?

A. Yes.

Q. When the procedure goes in such a way that the fetus is drawn out in parts, how does the disarticulation of the fetal parts occur?

A. It occurs because you have the fetal part drawn outside of the cervix, and then there is a counter-pressure that occurs at the internal os. And when you pull, the—it disarticulates that part.

Q. So, is the part that is being disarticulated inside the uterus or outside of the uterus at the moment of disarticulation?

A. Outside.

Q. Can it be outside the woman's body?

A. Yes.

Q. And you had said that sometimes when you apply traction to the fetus it comes out intact up to point where the calvarium lodges; is that correct?

A. Yes.

[70]

Q. In that circumstance, what do you do to complete the procedure?

A. Well, there are two things you can do. You can disarticulate at the neck, or what I prefer to do is to just reach in with my forceps and collapse the skull and bring the fetus out intact.

Q. So when you—in the first scenario where you disarticulate, would you consider that to be an intact D&E?

A. No.

Q. Do you have a preference in your medical practice between D&E's that result in disarticulation and D&E's that result in intact extraction of the fetus?

A. I absolutely prefer intact extraction.

Q. Can you explain why that is?

A. Because it involves fewer instrument passes, and as I explained earlier, each instrument pass there is a small risk of injuring the uterus. And because it is faster, generally.

Q. When you are performing a D&E, when you are beginning to apply traction on the fetus to bring it out, do you take steps to try to keep the fetus as intact as possible?

A. If I know I have good dilation and I reach in and the fetus starts to come out and I think I can accomplish it, the abortion with an intact delivery, then I use my forceps a little bit differently. I don't close them quite so much, and I just gently draw the tissue out attempting to have an intact [71] delivery, if possible.

Q. Just to be clear about this, in those situations where you are able to bring it out intact, but the calvarium lodges at the os, why does it lodge there? Why can't you just extract the entire fetus?

A. It is the biggest part of the fetus. Sometimes the dilation isn't enough for it to come through.

Q. In your practice, Dr. Paul, how often do you perform D&E's involving intact delivery to the point where the calvarium lodges at the cervix?

A. I am guessing, because until this case happened I didn't pay much attention to it. It was just a variation of the way I did D&E. But I am guessing 1 to 10 to 1 to 20 maybe of the procedures I do.

Q. Of the D&E procedures?

A. Yes, of the D&E procedures.

Q. What determines whether the procedure will proceed with disarticulation versus whether there will be an intact extraction?

A. It's primarily the amount of dilation.

Q. And before beginning the procedure, can you predict if you will have enough dilation to bring the fetus out with an intact extraction?

A. No, I can't.

Q. But if you have enough dilation to do so, do you attempt [72] that?

A. Yes.

Q. Dr. Paul, you've said that the one of the reasons why you prefer the intact extraction is because of the reduction of instrumental passes; is that correct?

A. Yes, that's one reason.

Q. Are there other advantages in your opinion in bringing the fetus out intact?

A. I mentioned that it tends to be faster, and therefore you may have less bleeding and less discomfort for the patient. Also, what I find advantageous is that I know I have removed the whole fetus. When you do a

disarticulation D&E, you know, sometimes it is not as easy to tell that you have all of the parts. So, if I have an intact fetus, I know I have removed that entire pregnancy.

Q. What happens in a disarticulation D&E if some tissue actually does remain in the uterus?

A. You can get bleeding or infection.

Q. And do you think it is possible to leave some tissue in the uterus even if you are doing the procedure under ultrasound guidance?

A. I think it is possible to leave a small part or to leave part of the placenta.

Q. And would even a small piece of tissue or placenta result in possible complications?

[73]

A. Yes. I have always been surprised of how little it takes.

Q. Dr. Paul, how long does the evacuation part of the D&E take when the fetus is disarticulated in the process?

Q. It really varies, but generally 10 to 15 minutes.

Q. And what is a typical length of the evacuation part of the procedure if the fetus remains intact?

A. It is usually much quicker. I have had it happen in a minute or two.

Q. In your medical practice, Dr. Paul, have you personally ever perforated a woman's uterus in the process of doing a D&E abortion?

A. Yes.

Q. And has it ever happened that you've perforated a woman's uterus in circumstances where you extracted the fetus intact or relatively intact?

A. It has only happened a couple of times, but it hasn't been—those two times was not associated with an intact extraction.

Q. You testified earlier, Dr. Paul, that the fetus can be alive when the evacuation begins; is that correct?

A. That's right.

Q. When in the course of the abortion does the fetus—does fetal demise occur?

A. I don't know for sure. I certainly know that if I deliver intact and collapse the skull that demise occurs.

[74]

Q. After the evacuation part of the procedure is complete, what do you do to complete the abortion?

A. I use suction to remove any placenta that may be left in the uterus. I also use an instrument called a curette. It is a little spoon-like instrument just to gently go over the walls of the uterus and just be sure that anything feels—the uterus feels empty.

Q. Dr. Paul, I am going to ask you some questions about the impact of this law on your medical practice.

MS. GARTNER: And, your honor, we have a blowup of the act, if you don't mind.

THE COURT: Sure.

BY MS. GARTNER:

Q. Dr. Paul, this chart contains the operative portions of the law that is at issue in this case. Can you just briefly review it so you can recollect the language?

Dr. Paul, are you concerned about the potential impact of this law on your medical practice?

A. Absolutely.

Q. Can you outline your concerns for us?

A. Well, my overriding concern is that if I continue to practice abortion, second-trimester abortions, in the way I believe is the safest for women, that I could be in prison.

Q. In your opinion, could this law be understood as banning some of the D&E's that you do?

[75]

MR. QUINLIVAN: Your honor, objection. It is our position that question of the interpretation of the law is not something that is subject to expert testimony. That is a subject that the court will consider after arguments by both parties. But it is not something that is properly subject to an expert's opinion.

MS. GARTNER: Your honor, I think it would be helpful—and obviously the final determination on this is your honor's—but I think it would be helpful for Dr. Paul to explain how she used these terms and how she thinks that these terms, which are not necessarily clear on their face, would apply to her specific medical practice and how she does abortions.

THE COURT: I am going to permit it.

MS. GARTNER: Thank you.

BY MS. GARTNER:

Q. Dr. Paul, could this law be understood as banning some of the D&E's that you do?

A. Yes.

Q. If you look at the law, it states that: "The term 'partial-birth abortion' means an abortion in which the person performing the abortion deliberately and intentionally vaginally delivers a living fetus." Do you see that language?

[76]

A. Yes.

Q. What does the term "vaginally delivers" mean to you as an ob/gyn?

A. "Vaginally delivers" means the fetus comes out through the vagina.

Q. And what does the term "living fetus" mean to you?

A. Well, "living" could be when there is a heartbeat detected on ultrasound, which could be as early as five weeks gestation. "Fetus" usually applies to the products of conception at 10 weeks and up. So if I put the two together, I would say a fetus at 10 weeks gestation, or more, that has a heartbeat.

Q. And you said that the term "fetus" was used beginning at 10 weeks gestation; is that right?

A. Ten weeks LMP, yes. Before that the products of conception are known as an embryo.

Q. In your mind is the term "living fetus" equivalent to the term "viable fetus"?

A. Absolutely not.

Q. In the D&E's that you do, do you ever deliberately and intentionally vaginally deliver a living fetus as part of the procedure?

A. Yes.

Q. Dr. Paul, continuing reading in this definition, it says that—just to repeat what we have already gone over—that:

> "The abortion occurs such that the physician [77] deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother."

Do you see that?

A. Yes.

Q. When the law says that "any part of the fetal trunk past the navel" is outside the body of the mother, what do you understand that to mean?

A. Well, it could mean a couple of things. One is that the fetus has come out far enough that the fetal body above the navel is outside of the cervix. The other—outside the body of the mother. And the other is that if you were to disarticulate a fetal part that was above the navel, like a limb with part of a shoulder, I would think that that would also apply.

Q. So, just to be clear about that, as you read this law, does the fetus have to be delivered intact up to the point where the calvarium lodges at the cervix for a violation to occur?

A. No.

Q. Does it have to be brought out intact to any point for a violation to occur?

A. It has to be brought out—one scenario is that it's [78] brought out past the navel intact. And the other is that, as I say, to disarticulate a part above the navel, and then continue to put your forceps in to deliver the rest of the fetus.

Q. And in doing D&E's do you ever deliver the fetus to the point where part of the fetal trunk intact with the rest of it is outside the body of the mother?

A. Yes.

Q. Do you ever deliver the fetus such that a disarticulated part of the fetal trunk past the navel is outside the body of the mother?

A. Yes.

Q. And does that ever happen when the fetus is still living?

A. Yes.

Q. Dr. Paul, continuing to read this definition, it says that the fetus is—just to summarize it—is brought outside the body of the mother to the point we have just discussed:

> "For the purpose of performing an overt act that the person knows will kill the partially-delivered living fetus."

Do you see that language?

A. Yes.

Q. Let me ask you first, do you understand the term "overt act"?

A. Not really.

Q. I will just leave that. In those circumstances that you've [79] just described to me in doing a D&E where

the fetus has been brought out in a way that could be described as being to a point where a part of the fetal trunk past the navel is outside the body of the mother, what do you do to complete the abortion?

A. I either disarticulate at the neck, or I put my forceps in and collapse the skull and complete the delivery.

Q. And in your opinion, would those steps be lethal acts that the fetus couldn't survive if it were alive before you did them?

A. I have no doubt that collapsing a skull or disarticulating at the neck would cause fetal demise.

Q. And then after taking those steps, either collapsing the calvarium or using disarticulation, do you then complete the procedure?

A. Yes.

Q. In the abortions that you have done where this has occurred where you brought the fetus out intact up to the point where the head lodges at the cervix, did you deliver the fetus to that point for the purpose of compressing the calvarium?

A. Of course not. I did it to empty the uterus.

Q. Dr. Paul, now that we have gone through the act in this way, are you still concerned about the impact of this law on your practice?

A. Oh, absolutely.

[80]

Q. Do you find any comfort in the "for the purpose of" language in this statute, given that you've told us that you don't bring the fetus out to that particular

point for the purpose of collapsing the calvarium or disarticulating at the neck?

A. I find no comfort in that. I mean, I know what my purpose is. That my purpose in bringing the fetus out past the navel, the fetal trunk out past the navel is to empty the uterus in the safest way possible. Yet, this language implies that I have this other purpose, which is to kill the fetus. So, to me, it's like—kind of like there is an elephant in the room besides me and my patient. It is not just me being allowed to do an abortion in the way that I think in my medical judgment is safest for a woman, but there is somebody judging what my purpose is in bringing the fetus out a certain way. And I don't feel like I can practice medicine well being second-guessed by a third party about what my purpose is in completing and in doing a certain act during an abortion when that person also has the power to put me in prison.

Q. Thank you.

MS. GARTNER: Your honor, may I put up a second chart?

THE COURT: Yes.

BY MS. GARTNER:

[81]

Q. Dr. Paul, this is actually the beginning part of the statute that we have been discussing. And this is the portion of the law that contains the life exception to the act, which is stated in the second sentence in that paragraph. Could you just read that to yourself, please? And, Dr. Paul, when you were teaching in a staff position at the University of Massachusetts Medical

Center, did you perform abortions for maternal health conditions?

A. Oh, yes.

Q. And was that a regular part of your practice there?

A. Yes.

Q. In your opinion, would the life exception to this law enable physicians to perform abortions in all situations where a pregnant woman's life is at risk from continuing the pregnancy?

A. No, it is not how I would interpret this language.

Q. What—why do you think this wouldn't cover all situations where a woman's life was at risk from the pregnancy?

A. My objection really revolves around that word "necessary." It says that:

> "This subsection does not apply to a partial-birth abortion that is necessary to save the life of a mother."

But it doesn't say who decides if it is necessary. There is nothing that says "is necessary within the judgment of [82] a treating physician."

It just says "necessary." So who determines if it is necessary? And is it possible that, again, a physician who is treating a woman could be second-guessed about that decision that it was necessary?

The other thing that I have a problem with with this is that it says "that it is necessary to save the life of a mother."

Well, there is always the alternative of hysterotomy and hysterectomy. But in my opinion, that is not a real alternative for women because of the high rates of morbidity and mortality that are associated with that procedure.

Q. Dr. Paul, earlier this morning you testified generally about the overall safety of second-trimester abortions and the relative safety of abortion and carrying a pregnancy to term. But we didn't focus specifically on the relative safety of the different second-trimester abortion methods. I would like to just go over that briefly with you. And talking first about the morbidity associated with the different second-trimester abortion methods. And I would ask you to look back at the exhibit there that is the Binkin article, which was Learned Treatise 15.

Dr. Paul, can you tell me what conclusions the JPSA studies reached about the relative safety of D&E and induction abortions?

[83]

A. As you can see from this table here, these are major complication rates for 100 procedures. So this is a percent. And these are the induction methods here (indicating) instillation, saline instillation, prostaglandin instillation (indicating). And this is the D&E method (indicating).

As you can see, in general, the rates of major complications by JPSA study were lower for D&E than they were for the instillation, induction abortion methods that were used at that time.

Q. Dr. Paul, can you draw any conclusions from the JPSA studies about the safety of D&E abortions in

which the fetus was extracted intact or relatively intact?

A. Well, JPSA didn't analyze that separately. It is my opinion that—again, because I consider intact delivery just a variant of D&E—that if you had a quarter of a million women involved in the JPSA studies that you definitely had cases of abortions in which the D&E was accomplished with intact delivery.

Q. And then, Dr. Paul, I would like you to look again briefly at the Lawson article that we discussed earlier, which is Exhibit 63, which will be on the screen now.

In this article, if could you focus your attention on table roman numeral III, on page 1368, which is here (indicating). And, again, the Lawson data, is that mortality data for abortion?

[84]

A. Yes.

Q. And does this table contain a summary of the CDC data on abortion-related mortality broken down by what procedure was performed?

A. Yes, it does.

Q. And what do these CDC data tell us about the relative mortality of D&E and induction abortions prior to 16 weeks gestation?

A. Again, these are case fatality rates or death rates expressed as the number of abortion deaths per 100,000 legal-induced abortions.

And here, evacuation they separate out D&E. They call it "evacuation" here. And then, you have the instillation methods, are which are the induction

methods that were used again at the time of the JPSA study of the—at the time that this was collected.

And what you see here is that prior to 16 weeks, that evacuation has a lower risk of death than instillation.

And at 16 weeks and up, the rates are in the same ballpark.

Q. And what do these CDC data tell us about the relative mortality of either D&E or induction compared to hysterotomy or hysterectomy?

A. There's hysterectomy, hysterotomy. And as you can see, the death rates associated with hysterotomy and hysterectomy are much higher. And I would say prohibitively high. There 16 to [85] 20 weeks it is over a hundred deaths per 100,000 procedures.

And here, at over—at 21 weeks and over, it is 274 deaths.

So, they are just incredibly much higher than the death rates associated with the other methods of abortion.

Q. And just to make the record clear, Dr. Paul, in the 16 to 20 week time frame, what is the approximate case fatality rate for D&E and induction abortion?

A. For D&E it is approximately 6.5 per 100,000 procedures; for instillation 7.9, for 100,000 procedures.

Q. What about over 20 weeks gestation?

A. For D&E, 11.9; and for instillation, 10.3.

Q. Now, Dr. Paul, you had testified earlier that the JPSA studies involved older methods of doing D&E and induction; is that correct?

A. That's right.

Q. Are there any studies that specifically compare the relative risks of D&E and induction abortions, as those procedures are currently performed?

A. There's a couple of small studies.

Q. Can you describe those for me?

A. One is by Autry and colleagues. And what they did was a historical cohort study, basically looking back into medical records identifying women who've had a medical abortion, which would be the induction type of abortion and women who had D&E abortion, and then determining what the complications were with [86] those procedures.

And what they found was a higher rate of complications with induction methods than with the D&E. But it had to do mostly with retained placenta, which means that there was quite a high rate of retained placenta associated with the induction abortion that required surgical removal of the placenta through a curettage technique or by manual removal.

They also had one incidence of uterine rochsho (phonetic) associated with the medical induction procedures.

Q. In your practice, Dr. Paul, in providing induction abortions, can you describe briefly what's involved when there's a retained placenta as part of an induction abortion?

A. I did a lot of induction abortions at the University of Massachusetts Medical Center, and the medication was often successful in getting the fetus out, but the placenta remained in the uterus.

Generally, you would wait and wait. And it's kind of standard that if two hours after the delivery of the fetus the placenta has not yet delivered, that you take some kind of intervention to remove the placenta.

So, you could try to remove it manually, it's pretty uncomfortable; you can reach up and try to actually get it with your hands, or you can do basically a suction and curettage removal of the placenta. I know at the university we often put people to [87] sleep to do that. I mean, it was a big deal for women to have gone through a whole labor process thinking they weren't going to have surgery and then end up having to be put to sleep to have the placenta removed.

Q. What are the risks—you said there was a general rule of thumb to remove the placenta after two hours if it hadn't delivered on its own.

What were the risks if the placenta remained inside the uterus longer than that?

A. That's been looked at in the literature, and basically there is an increase incidence of bleeding and fever if you have it in there for longer.

Q. Other than the Autry study, are you aware of any other recent studies comparing the modern methods of D&E with modern methods of induction abortions?

A. There is a small randomized trial by Dr. Grimes.

Q. Is that the same Dr. Grimes who is the co-director of the JPSA studies?

A. Yes, it is.

Q. Can you describe that study for me, please?

A. It was a pilot randomized study—

MR. QUINLIVAN: Your honor, I have an objection. That study was not disclosed in either of the—either the expert report or the rebuttal expert report that was submitted by Dr. Paul.

[88]

MS. GARTNER: I believe that Dr. Paul testified as to this in her deposition.

(Pause in the proceedings.)

MS. GARTNER: Your honor, I apologize, I don't have the page handy. I don't think this is a central point. We have other witnesses who will testify about that study, so we can move forward on that.

THE COURT: All right. Without some reference, you have put the defense on notice to that study, she may not do so. If there is such notice, either in the expert report or the deposition transcript, I would permit it.

MS. GARTNER: I understand, your honor. I believe it was in the deposition, but I don't want to waste the court's time looking for it now.

BY MS. GARTNER:

Q. Dr. Paul, other than the JPSA studies, the Lawson study, and the Autry study that you've just talked about, are there other data or studies that would help to assess the safety of D&E abortions in particular?

A. Well, there are single institution reports of the experience of the institution of doing D&E's and generally confirming safety.

And the same with induction, I mean, there are single institution reports of experiences of random induction.

Q. What do those single institution reports generally show?

[89]

A. They generally confirm that they both are safe procedures, but that induction does have this problem of retaining the placenta very, very rarely during interruption.

Q. Are you aware of any data or studies comparing the relative safety of D&E with intact extraction to other second-trimester abortion methods?

A. No.

Q. In your opinion, is it surprising that there are no studies specifically looking at D&E's with intact extraction?

A. No.

Q. Why is that?

A. First of all, I think it's considered just a valiant, so I am not sure people ought to study it separately, but I—it also would be difficult to set up a study that looked at intact because, first of all, there is not—it would be hard to predict if the fetus were going to come out intact.

So, I am not sure how you would set up a study to really look at that in any kind of good way, and the other thing is, is that because there's—it's a little hard to explain—but basically, to set up a good randomized trial where you're putting women into groups, you know, one getting intact extraction, the other getting

disarticulation of D&E, right, in a way that does not introduce bias, the kind of biases that we see in studies and so forth, you would first have to be able to identify who would get those intact versus [90] disarticulation, I said, that would be hard to predict, but the other thing is that you would need very large numbers in each group in order to see if there was a difference in complication rates. One, because complication rates don't occur that often with abortion, right, complications don't occur that often with abortions, and the other is because the percentage of abortions that are done in the second—beyond the first-trimester are relatively small.

So, that just would make it very, very difficult to set up a really good randomized trial that could give you that information.

Q. Okay.

Is there any requirement in the medical profession that a medical technique be subjected to randomized trial before it's used?

A. No. We like when we have randomized trial, but it certainly is not a requirement before we use techniques.

Q. Are there other aspects of abortion practice other than the intact extraction variant of D&E that have not been subjected to randomized trial?

A. Could you repeat that question?

Q. Yes. Are there other aspects of abortion practice that have not been subjected to randomized trial? And by "other," I mean other than the intact extraction.

[91]

A. Yes. I mean, most of what we do in abortion has not been subjected to randomized trial.

Q. Dr. Paul, what is evidence-based medicine? What does that term mean?

A. Evidence-based medicine is a way of doing medicine that takes into consideration the scientific information that is available.

Q. And under the principles of evidence-based medicine, what should a physician do if there are no studies assessing the safety of a particular technique?

A. Well, basically evidence-based medicine says that if there is good evidence that one particular method should be used, then it is our responsibility to use that method.

But where that evidence is lacking or is inadequate, that we use our best clinical judgment to render the safest care possible to our patients.

Q. So, Dr. Paul, given the comparable safety, what you've testified as the comparable safety of D&E and induction beginning at about 16 weeks gestation, based on your experience providing abortions what are some of the considerations that go into a woman's decision to pick one procedure or the other if she's having a second-trimester abortion?

A. Patient preference go one procedure over the other in my experience and from my reading of the literature. Induction abortion can be pretty trying to women, and women tend to have [92] a preference for the shorter D&E procedure.

Q. Dr. Paul, just to conclude and go back again to the statute in this case, what impact would this law have on your practice if it took effect?

MR. QUINLIVAN: Objection, your honor, asked and answered.

THE COURT: Overruled.

THE WITNESS: Well, I think it would have a tremendous impact on my practice. I would be forced with a decision I would have never faced before in medicine and that is as to whether to continue to do procedures in a way that I think are safest for women because if I did so, I would risk imprisonment.

And I have dedicated a lot of my life and career and been pretty adamant about wanting to provide care to women, so this would be a very difficult personal and professional decision to me—for me as to whether I could continue to do second-trimester abortions.

BY MS. GARTNER:

Q. If this law took effect, would it affect how you teach D&E abortions?

A. I think it would.

I would have to make a decision about whether I could teach all methods, if I could teach about intact extraction, some of the things that might be violated by this [93] law. I would, at the very least, feel a responsibility to inform those whom I am teaching that they could—that they would risk imprisonment if they performed an D&E in a particular way.

Q. And would, if this law were to take effect, would it affect your relationship with your patients in your opinion?

A. Yes. I think fundamentally my relationship with my patients is based on trust, and part of that trust is that I am going to give them the best care possible and I am going to do a procedure the way I deem that is safest at the time. So, that fundamental trust would be compromised.

And there's also a part of the law that says something about that civil action could be taken against me if a spouse—if I didn't obtain the consent of a spouse or, in the case of a teenager, her parents before I did a procedure, that might violate this act.

So, to me, that really violates the most fundamental tenets of patient confidentiality. There is no requirement in California for me to tell a parent about—to get the consent of a parent to do an abortion on a minor. So what's that mean now; suddenly I have to do that?

There is certainly nowhere that the spouse has to give permission for a woman to have an abortion, so the whole thing about patient confidentiality, the whole basis on which [94] my trusted relationships with patients are built is compromised.

* * * * *

[CROSS-EXAMINATION BY MR. QUINLIVAN]

* * * * *

[PAUL—CROSS EXAMINATION]

* * * * *

[103] procedure is safer than the disarticulation D&E procedure is based on your intuition and your clinical experience?

A. On my clinical experience and the clinical experience of all of the physicians with whom I have spoken.

Q. Are you able to quantify in any way the advantage you believe that the intact D&E procedure has over disarticulation D&E?

A. To quantify it, no.

Q. Do you consider that disarticulation D&E's are generally safe?

A. Yes.

Q. And in your experience, how many complications have you had with the disarticulation D&E procedure?

A. I don't recall exactly. I do know that the two cases of perforations I had were with disarticulation D&E.

Q. It's true, Dr. Paul, that with respect to Planned Parenthood Golden Gate, you don't record on your forms whether or not the procedure was performed intact or not; is that correct?

A. That's right.

Q. So, would you be—strike that. Dr. Paul, it's true, isn't it, that there are examples in the medical literature where physicians have thought that a particular procedure was safe and effective * * *.

* * * * *

[105] electronic fetal monitoring actually led to higher cesarean section rates; isn't that right?

A. Universal use of electronic fetal monitoring, yes.

Q. That was not something that anyone had thought of prior to those studies being conducted; isn't that right?

A. People might have thought about it, but they didn't know it.

Q. Dr. Paul, would you agree that if a particular abortion procedure led to a higher rate of cervical incompetence, then other procedures that that would be a complication of the first procedure?

A. If that were proved, yes.

Q. And if you wanted to look at the outcome of cervical incompetence, you would have to follow women through their next pregnancy to determine whether there was any kind of difference in rates; isn't that right?

A. Yes.

Q. Just to be clear, you yourself are not aware of any data that has considered whether the intact D&E procedure might lead to higher rates of cervical incompetence as compared to other procedures, are you?

A. No.

Q. Have you yourself followed up with women who have undergone an intact D&E through their next pregnancy to determine whether their might be higher rates of cervical incompetence?

[106]

A. Well, I don't do prenatal care anymore, so I would not have seen them in the next pregnancy if they carried to term.

Q. The answer is "No"?

A. No.

Q. Is it also—would you agree that if a particular abortion procedure led to a higher term of preterm—

THE REPORTER: I'm sorry. Can you start again?

BY MR. QUINLIVAN:

Q. Would you agree that if a particular abortion procedure led to a higher rate of pre-termed deliveries than other abortion procedures than that would also be a complication?

A. Yes. If you really knew that. If the complication is an odd term to use, generally that is kind of what we call long-term sequelae, it is different than the kind of complications that are typically measured after an abortion procedure.

As you can see from the JPSA study, that's not a complication that was ever looked at. So I just want to be clear on our definitions of complication.

Q. Understood.

And I guess my question is, there can be complications that occur potentially months or years after the abortion procedure, not just right when the abortion procedure takes place; isn't that right?

A. There is no evidence that there is long-term adverse * * *.

* * * * *

[107]

* * * * *

Q. Given what you just testified when I asked you the question about cervical incompetence, you haven't followed through with women who have undergone the

intact D&E procedures to see if that has led to a higher rate of pre-termed deliveries, have you?

A. No. As I say, I probably wouldn't even remember which ones had intact and which had disarticulation D&E because I don't specifically note it on the chart.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, DEFENDANT

TRANSCRIPT OF PROCEEDINGS
Mar. 29, 2004
Volume 1

BEFORE THE HONORABLE
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* * * * *

[KATHERINE SHEEHAN, M.D. – DIRECT EXAMINATION]

[151]

* * * * *

Q. Good morning, Dr. Sheehan. Have you come to court today prepared to provide your opinions about the partial-birth abortion ban act and its impact on your practice?

A. I have.

Q. Before we get into your opinions, I would like to do a couple of background questions; is that okay? Are you a physician?

A. I am.

Q. In what fields?

A. I'm trained in OB and GYN.

Q. Are there any other fields in which you practice or are trained?

A. I did a Subspecialty Fellowship in Reproductive Endocrinology.

Q. And what is reproductive endocrinology?

A. That is the speciality regarding hormones and having to do with reproduction, male and female reproduction.

Q. And you indicate that your were trained in obstetrics; is that correct?

A. That's correct.

Q. Do you with currently practice obstetrics?

A. I don't.

Q. And why is that?

A. I found that during my training that I really enjoined [152] taking care of women. I enjoyed the actual practice of medicine for women and therefore focused more on gynecology. It also allowed me a little bit more time to raise my family.

Q. Are you board certified?

A. I am.

Q. In what areas?

A. OB/GYN.

Q. And what is your current position?

A. I'm currently full-time medical Director of the Planned Parenthood Affiliate of San Diego and Riverside counties.

Q. And how long have you held that position?

A. Since 1981.

Q. So close to over 20 years?

A. Correct.

A. Can you tell me a little bit about Planned Parenthood San Diego Riverside counties? First of all, how many health care centers does that affiliate have?

A. We have seventeen health care centers.

Q. And where are they located?

A. They are spread throughout the counties of San Diego and Riverside.

Q. And what types of patients does Planned Parenthood San Diego Riverside county serve?

A. We see primarily young healthy people for their contraceptive needs, evaluating pap smears for women and [153] evaluating abnormal pap smears. We also see young men for contraception and for STD testing. We have an HIV screening program.

We also have a midlife program, which is for women of middle age. We have a prenatal program. We have a sterilization program for both men and women. And we have significant abortion program.

Q. And how many patients does Planned Parenthood San Diego Riverside county see each year?

A. We see over a hundred thousand patients.

Q. And as Medical Request Director, are you in charge of—what does your position entail?

A. I am responsible for all the medical care that is provided at the affiliate. I supervise all the physicians and the midlevel clinicians which are nurse practitioners, nurse midwives, physicians assistants.

Q. So you oversee all the medical care and you supervise the various physicians?

A. Correct, and I am responsible for the medical protocols of the operation, the standards that we operate under.

Q. How many physicians does Planned Parenthood San Diego have that you supervise or oversee?

A. We have approximately 11 or 12.

Q. And what about the other medical personnel that you were just talking about?

[154]

A. We have over—probably over a hundred midlevel positions and some part-time positions.

Q. Does Planned Parenthood San Diego Riverside County offer abortions?

A. Yes.

Q. Does it do so at all of the 17 health centers?

A. No. We provide abortion services only at three of the centers, surgical abortion services. I should say we provide medical abortion services at all the family planning centers.

Q. To what gestational age do you provide medical abortions?

A. We provide medical abortion up to sixty-three days or nine weeks.

Q. And you said you provide those at all of the family planning?

A. Family planning.

Q. And what do you mean by medical abortions?

A. I mean, abortions that are induced by giving the women medicine, usually mifepristone.

Q. And you indicated that you provide surgical abortions at three of the health care centers; is that right?

A. Correct.

Q. And what do you mean by "surgical abortions"?

A. I mean abortions that are provided as—by the means of surgery.

Q. And up to what gestational age does Planned Parenthood San [155] Diego Riverside County provide surgical abortions?

A. We provide it up to another twenty-four weeks.

Q. As part of the surgical abortions that you provide, do you provide those due to the presence of a fetal anomaly?

A. We frequently do that.

Q. And why do you do that?

A. Our affiliate has become basically the main referral center for all of California South of L.A. for few anomalies. We receive referrals from the Kaiser-Permanente Group. We receive them from the largest medical groups in that area. Even UCSD refers some of their cases to us.

So we have become basically the primary source for fetal anomaly terminations in that area. We are the only center that goes past 18 weeks in the area.

Q. And that is the only center for all circumstances, including fetal anomalies, or just the fetal anomalies past 18 weeks?

A. I'm sorry. I don't understand.

Q. Well, you indicated you are the only center that provides abortions after 18 weeks gestation in the San Diego area; is that right?

A. There is one other provider who will go past 18 weeks for fetal anomalies.

Q. And do you know what percent of the second-trimester [156] abortions that are performed at Planned Parenthood San Diego are for fetal anomalies?

A. Since we are becoming the sole referral source, our numbers are definitely increasing. I would say it is in the range of 15 to 20, and possibly 25 percent.

Q. And what type of fetal anomalies are referred to Planned Parenthood San Diego?

A. It's across the board. We have had three cases of conjoined twins, we have anencephaly, Potter's Syndrome, which is a condition where the kidneys don't develop. We have certain—Downs Syndrome is the most common, many other genetically-abnormal pregnancies.

Q. What is anencephaly?

A. Anencephaly is when the brain doesn't develop.

Q. And are all those fetal anomalies that you just mentioned chromosomal?

A. No. Some of them are structural, such as the renal agenesis, Potter's Syndrome.

Q. What is renal agenesis?

A. That's where the kidneys don't develop.

Q. And are some of them structural?

A. Yes.

Q. And could you give us some examples of structural fetal anomalies that your affiliate deals with or sees?

A. The lack of development of the kidneys would be one example [157] of that. Another example would be a condition called amniotic bands, when there is not enough amniotic fluid in the uterus and so the membrane becomes bands, and they cut off the circulation for the fetal limbs and so there is no development of the hands or the feet. There is—basically the circulation is cut off, and so the limbs don't develop.

Q. And you also indicated you had recently seen three cases of conjoined twins?

A. I have.

Q. Are there any other structural fetal anomalies that your affiliates have seen?

A. We have seen numerous structural anomalies. Just last week I saw a woman with several anomalies, which were cardiac malformations, hand malformations and formations of the bones of the face.

Q. Are some of these anomalies fatal?

A. Absolutely.

Q. Give me some examples of some of the ones which you've seen that are fatal?

A. Potter's Syndrome is incompatible with life. Anencephaly is incompatible with life. This one that I just mentioned with the cardiac malformations and cystic kidneys is incompatible with life.

Q. So in addition to surgical abortions, does Planned Parenthood San Diego affiliate offer induction abortions?

[158]

A. We don't offer induction abortions.

Q. And why is that?

A. We don't have the physician time it requires keeping a physician at the hospital for many hours, and we just don't have the manpower.

Q. Now, you indicated that you supervise 11 physicians at the affiliate. Do all of those physicians perform abortions?

A. No, two of them do vasectomy.

Q. But the remaining nine do?

A. Yes.

Q. And do all of those physicians perform second-trimester abortions?

A. No, they don't.

Q. How many do?

A. Three.

Q. Do you perform second-trimester abortions?

A. I do.

Q. Is that a significant part of your clinical practice?

A. It is.

Q. And up to what gestational age do you provide second-trimester abortions?

A. Up to 24 weeks.

Q. How do you ascertain that gestational age?

A. The ascertainment of gestational age is not a hundred percent accurate science, but it starts with the woman's [159] history of her last menstrual period, as was mentioned earlier today, and an examination and also an ultrasound evaluation.

Q. Do you use any particular measurements to determine that it's up to 24 weeks?

A. We use as many measurements as we can make using the ultrasound. The primary ones are biparietal diameter. We have diameter circumference and the fetal length—I am sorry—femur length, f-e-m-u-r.

Q. What is the biparietal diameter?

A. That's the distance—

THE COURT: Why don't you spell that word?

THE WITNESS: B-I-P-A-R-I-E-T-A-L. The parietal bones are on either side of the head. The biparietal diameter is from this side of the head.

BY MS. PARKER:

Q. And up to what biparietal diameter do you offer second-trimester abortions?

A. We go up to 56 weeks.

Q. And does your affiliate ever go beyond 24 weeks?

A. No.

Q. And why is that?

A. It has been an interpretation based on the viability issue.

Q. So you indicated that—let me back up. What types of abortions do you offer in the second-trimester at your affiliate?

[160]

A. We provide abortions by suction up until about 16 weeks, and then dilation and evacuation after that.

Q. And what types do you offer, do you personally perform?

A. Both of them.

Q. And approximately how many surgical abortions have you performed in your career?

A. It's a difficult thing to try to compute, but I would guess around 30,000 abortions in my career.

Q. And how many of those were in the second-trimester?

A. I would say approximately 30 percent of them.

Q. You said 30 percent?

A. Right.

Q. So it would be about 9,000?

A. Yes.

Q. Do you have clinical experience performing inductions?

A. I do, during my residency.

Q. Do you currently perform induction abortions?

A. No.

Q. And why is that?

A. As I mentioned before, we just don't have the time to send somebody to the hospital for hours at a time.

Q. And you did do so during your residency?

A. I did.

Q. Approximately how many induction abortions did you do during your residency?

[161]

A. I would say approximately 300.

Q. So in addition to serving as the Medical Director of Planned Parenthood San Diego, do you have any responsibilities with regard to Planned Parenthood Federation of America?

A. I do in that I sit on the national—I have sat on the National Medical Committee, which is an advisory committee made up of experts who advise the Planned Parenthood Federation Board on the medical policy. And I also serve as an affiliate reviewer.

Q. And what do you do as an affiliate reviewer?

A. Twice a year I serve on a group of people who go to the affiliates and review the affiliates' performance primarily in the medical field. Suellen Craig's testimony mentioned the many different factors that are looked at at the affiliates to ascertain if they are providing excellent services that meet the standards of the Federation.

But the physician goes on this committee basically to review the medical services that are being provided at the affiliate.

Q. Is that part of the accreditation process that the Planned Parenthood Federation does at each of the affiliates?

A. That's correct.

Q. It is the medical aspect of that?

A. Correct.

Q. And you are part of that committee?

[162]

A. Correct.

Q. So in addition to those two sort of responsibilities, Medical Director and serving on the medical committee for Planned Parenthood Federation, do you do anything else in your professional capacity?

A. I have a small private practice, as well.

Q. Okay. Why don't you tell us a little bit about that, as well?

A. I have a very nice small private practice for about 12 years in an area near San Diego. And when I was asked to go back to the affiliates as a full-time medical director in 1997, I requested that I be allowed some time to continue my private practice. So one day a week I see my own private patients.

Q. What services do you offer in that practice?

A. General gynecology.

Q. Do you do anything else professionally? Do you teach?

A. Thank you. I am on the faculty at UCSD. I am a clinical faculty member at University of California San Diego. And I teach the residents in the reproductive medicine program. Primarily we teach them abortion

provision. We also have some residents who choose not to go through the abortion program, and they do family planning services.

I also teach the Navy residents in OB/GYN who come to learn abortion services.

Q. And the naval residents, where do they come from?

[163]

A. The U.S. Navy has a residency program in San Diego at the Naval hospital.

Q. Does the U.S. Navy have a medical school in San Diego?

A. No.

Q. Where is that located?

A. Bethesda, Maryland.

Q. Do you do the training at the hospitals or do you do that at Planned Parenthood's clinics or health centers?

A. I do that at the Planned Parenthood centers.

Q. And what do you train the reproductive medicine residents in?

A. Primarily in first and second-trimester abortion care, but also in family planning.

Q. Do you train them how to perform abortions?

A. Yes.

Q. And what particular methods of abortions?

A. We train them in the provision of medical abortion, and early surgical abortion, which we also call

manual vacuum abortion. And we use suction aspiration and dilation and evacuation.

MS. PARKER: Your Honor, may I approach the witness?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Sheehan, I show you what has been marked Exhibit 66. Do you see that?

[164]

A. I do.

Q. And what is that?

A. This is my C.V.

Q. Did you prepare it?

A. I did.

Q. Is it current?

A. It is.

Q. Is the information in it accurate and correct?

A. It should be.

Ms. Parker: I would like to offer exhibit 66 into evidence.

THE COURT: Any objection?

MR. SIMPSON: No objection, Your Honor.

THE COURT: Admitted.

THE CLERK: Sixty-six into evidence.

(Plaintiff's Exhibit 66 was received in evidence.)

MS. PARKER: And, Your Honor, I would like to move to qualify Dr. Sheehan as an expert witness in the areas of gynecology, and all areas of abortion practice.

THE COURT: Any objection?

MR. SIMPSON: Your Honor, subject to our questioning her further on cross-examination—

THE COURT: Do you wish to question her now?

MR. SIMPSON: No, not in voir dire; simply in [165] relation to her qualifications on cross. We have no objection to admitting her as an expert.

THE COURT: All right. She will be admitted.

MS. PARKER: You want me to move on?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Sheehan, you indicated you were here to provide your opinions on the partial-birth abortion ban act and the impact on your practice; is that right?

A. Correct.

Q. Can you give us a general overview of what those opinions are going to be?

A. My opinion is that the act could strongly inhibit the way I normally practice abortion care for my patients in the later part of the second-trimester.

Q. And do you have any opinions about the overall safety of the procedures that appear to be banned by the act?

A. I feel strongly that abortion care as we provide it in our affiliate, which is to provide the safest possible D&E care, often would violate the understanding or my understanding of this act.

Q. So you indicated that you use dilatation and extraction in the second-trimester; is that correct?

A. Correct.

Q. And do you have a goal when you perform that particular [166] procedure?

A. My goal is to complete the termination of the pregnancy as quickly and safely for the woman as possible.

Q. And how do you do that? How do you attempt to achieve that?

A. One of the crucial things about dilation and extraction is to provide accurate cervical dilation. And this is accomplished over one or two days before the procedure by using osmotic dilators to achieve adequate dilation for the procedure. And then, the procedure itself is done as quickly with as few passes with the forceps as possible, and to get the procedure done quickly.

Q. And what is the purpose of doing it with as few instrument passes as possible?

A. I think the crucial thing to understand about D&E is that you are putting instruments through a small aperture, which is the cervix, into the uterus. It is a totally blind procedure. We do have ultrasound available during the procedure to help guide us, but it is not a perfect adjunct. You're putting large forceps into a blind space to try to extract fetal parts that are larger than the aperture of the cervix. It is a very risky condition, potentially, because if the forceps closes on, you know, the wall of the uterus or perforates through the wall of the uterus and closes on some other organ of the woman, there are serious complications and serious

things happen after [167] that. So, it's—it just makes sense to make that kind of maneuver as infrequently as possible.

Q. And what do you try to accomplish so you can do as few maneuvers as possible?

A. The essential thing is adequate cervical dilation.

Q. And the purpose of adequate cervical dilation is for what purpose?

A. The purpose of adequate cervical dilation is so that I have adequate room to put my forceps in and make the fewest amount of passes to be able to extract the fetal tissue.

Q. And you indicated there were some complications. I think that is the word you used. The more times you introduce the instruments into the uterus; is that right?

A. Correct.

Q. And could you describe what some of those could be?

A. Well, the main thing is allowing the forceps to go past the wall of the uterus. As the pregnancy gets further along in gestation, the wall gets thinner and thinner so it is actually possible to have put the forceps through the wall and not be absolutely certain that you know where you are.

It is also possible to close down those—that instrument on tissue that isn't actually fetal tissue, and then when you put traction on it, you can actually injure the uterus or injure other organs in the woman.

Q. What happens when that occurs?

[168]

A. One hopefully notices it right away; know that you have got a complication. You have to transport the woman to the hospital and perform an open surgery to evaluate the situation and fix it.

Q. And so that's—

THE COURT: Excuse me. Can I ask a question? Do you use the ultrasound with every procedure, every D&E procedure?

THE WITNESS: I do.

THE COURT: Is that standard?

THE WITNESS: I don't believe it is standard. I think in our affiliate it is standard, but when I go around and review other affiliates, it is not.

BY MS. PARKER:

Q. You indicated one of the reasons why you want to have as few instrument passes as possible was to reduce the risk of perforation or laceration?

A. Yes.

Q. Are there any—are there other reasons that you want to have as few instrument passes as possible?

A. The other thing I would say is that if I can do the procedure as quickly and with as few passes as possible then it reduces the anesthesia time. Our patients are deeply sedated to the point of actually being asleep. And this is a potentially risky situation for the woman that if she can't [169] breathe for herself or if she were to vomit and aspirate the contents of her stomach, this can be a potentially fatal condition.

So we try to have the woman under anesthesia as short of a time as possible. So completing the procedure as fast as possible with as few passes as possible is desirable.

Q. And are there other reasons that you can think of why you want to have as few instrument passes in the uterus as possible?

A. Well, each time you pass in and out of the uterus you have the potential of actually cutting the cervix with any of the sharp parts that might be coming out of the uterus, so you potentially raise your risk of laceration.

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Volume 2
Tuesday, Mar. 30, 2004

[178]

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Q. Before we resume with our discussion of how you perform a dilation and evacuation procedure, I just wanted to ask you a few more brief background questions, if that's okay.

A. Yes.

Q. In addition to your clinic practice at Planned Parenthood San Diego and your private gynecological practice, do you have any hospital privileges or do you ever do anything at any hospitals?

A. I do have, but I consider it a fairly unique situation within Planned Parenthood in that I am a fully fledged attending doctor at the Women's Hospital in San Diego. And so the patients at Planned Parenthood have the advantage of being able to have their pro-

cedures done at the hospital, if there are indications for them to need to be hospitalized and need that higher level of acuity.

Q. And what type of procedures would you do at the Women's Hospital in San Diego?

A. I have every Friday morning reserved for surgeries. [179] Usually they are tubal ligations, removal of ovarian cysts, general gynecologic care. But we can certainly reserve time to do D&E's, as well.

Q. And have you ever testified previously in any case involving an issue about abortion?

A. No.

Q. Have you ever testified previously in a case?

A. No.

Q. So let's now return to our discussion of D&E. Yesterday, you indicated that you performed D&E procedures in the late second-trimester; is that right?

A. Correct.

Q. And what is the gestational age up to which you perform those procedures?

A. Up to 24 weeks gestation.

Q. Do you do the same D&E procedure throughout the second-trimester of abortion?

A. Under 16 weeks I generally use misoprostol to allow a one-day procedure. I also use mainly suction to extract the fetal parts and placenta.

After 16 weeks, uniformly when you have laminaria inserted overnight and have more of an extraction sort of procedure.

Q. Let's focus our discussion on after 16 weeks up to about 24 weeks. Is that okay with you?

[180]

A. Yes.

Q. And I would like to start with how do you start the procedure? What happens when a woman first comes into the clinic who needs a later second-trimester abortion?

A. She goes through the general intake process, fills out her history forms and things like that. She meets with a counselor. She has all the information given to her about the potential procedure.

She has a thorough history reviewed with a clinical person, usually a nurse practitioner, a physical examination, an ultrasound to confirm the gestational age.

Q. Do you give every patient an ultrasound?

A. Yes, every single patient gets an ultrasound.

Q. What happens after the ultrasound?

A. We make a decision about whether we are able to proceed there in the clinic or if she needs to go to the hospital. She has anesthesia risks evaluated. As long as she qualifies for an outpatient surgery in our clinic, then we go ahead and start the procedure, being sure that she has had her informed consent obtained.

And the first step of the procedure is the insertion of the first set of laminaria.

Q. How many laminaria do you insert on the first day?

A. The first day there are two laminaria inserted.

Q. What is the purpose for inserting them on that day?

[181]

A. The process is started in terms of softening the cervix and starting the dilation so that a larger number of laminaria may be inserted at the next opportunity.

Q. How much do the laminaria swell up? We saw one yesterday. I think this one was used (indicating). Can you describe for us how much they swell up?

A. The laminaria start usually at about three or four millimeters of diameter, and they can swell three or four times up to over a centimeter.

Q. That is the first day. What happens after that?

A. The patient is discharged. She goes home. If she feels comfortable enough, she can go about her normal activities. Some of the women have a lot of cramping and have to stay at rest.

She comes back the next day. She is evaluated again. Those first laminaria are removed, and then a new set is inserted.

Q. Do you always use a second set in the later or after 16 or 18 weeks?

A. Our general rule is at 18 weeks there will be a second set of laminaria placed. It isn't always followed, particularly if a woman has a fetal demise. If the fetus has already died inside the uterus, the uterus is much more irritable, and we usually will use just one set of laminaria then.

Q. So you do the second set on the second day; is that right?

[182]

A. Correct.

Q. How many do you insert at that time?

A. It's not an absolute number. Generally, we try to put in as many as would fit comfortably. This is generally in the range of five to eight.

Q. Are you aiming for a particular amount of dilation?

A. There is a goal that we have in the clinic to try to obtain at least a minimum amount of dilation to make the procedure safe. And the rule that we use is that the dilation of the cervix in millimeters should be relatively equal to the gestational age in weeks.

So if the woman is at 20 weeks, then we would like to have 20 millimeters of dilation, or two centimeters.

Q. And can you predict the amount of dilation you will get?

A. It is highly unpredictable.

Q. Is there a minimum amount you need?

A. Yes. Without having adequate dilation, one isn't able to introduce the instruments into the uterus. And so absolutely the cervix has to be dilated an adequate amount.

Q. Can you control the amount of the dilation?

A. No. We try to get an adequate amount of laminaria in, but the laminaria dilate variably based on many factors, primarily what the nature of the patient's cervix is like.

Young teenagers with little, firm cervixes tend to not dilate as easily. A women who has had a delivery or two, [183] the cervix will dilate much more easily.

Q. In your opinion, is it ever possible to get too much dilation?

A. That is a desirable condition to have, plenty of dilation. So, no, I don't think you can have too much.

Q. How long do you leave the second set of laminaria in?

A. Again, overnight.

Q. So, she's had now two sets of laminaria two different days. She comes back, I take it, on the third day?

A. Yes.

Q. And then, is that the day that you start the actual procedure?

A. Correct.

Q. Could you describe for me what happens on the third day?

A. She is taken to the procedure room. An IV is started. She changes out of her clothes. She gets up on the table. It is a normal, like a pelvic exam table that you would go and have your pap smear on.

There is an anesthesia provider there, and anesthesia is begun so the patient can be calm and relaxed and comfortable during the procedure.

A pelvic exam is carried out to, one, remove the gauze and laminaria that have been put in the cervix; and then, also to assess the nature of the cervix, how dilated it is, how soft it is, how effaced it is. "Efface-

ment" is the process of [184] shortening of the cervix. The cervix starts out fairly long, and it opens up along with dilating.

We evaluate the presentation of the fetus, what part of the fetus is presenting at the cervix. I can feel if the cervix is adequately dilated up into the uterus and feel previous cesarean scar, things like that.

And then, we bring in the ultrasound machine and evaluate, again, for the presentation of the fetus.

Q. And, again, do you use the ultrasound with every patient at that time?

A. Yes.

Q. And after—and the ultrasound, you indicate you are doing that to figure out what the fetus presentation is?

A. Correct.

Q. And do you ever attempt to change the fetal presentation?

A. No, I don't. But certain presentations are more difficult to deal with, and I just want to know what I am dealing with.

Q. Okay. So after you have assessed the fetal presentation, what do you do next?

A. Then, a cervical block of local anesthetic is placed around the cervix, and the amniotic sac is ruptured, allowing the amniotic fluid to flow out.

And, then, using the forceps, I begin the procedure of extracting the fetal part.

Q. And how do you go about doing that?

[185]

A. I generally try using the ultrasound to find the small parts of the fetus, "small parts" being considered the extremities. I really prefer it if the lower extremities are presented first. I can grasp the lower extremities of the fetus, and using gentle traction, extract the tissue.

Q. And after you have done that, what do you have? What happens next?

A. I continue to put traction on the fetus tissue. If the cervix is adequately dilated, then the fetus will generally slide down through the cervix, and I continue to extract the tissue until it is completely extracted.

If the cervix is not so well dilated, then disarticulation and dismemberment happens.

Q. And how long—well, after the fetus is removed or extracted, what do you do?

A. I am sorry, how long after?

Q. Well, after you have extracted the fetus—

A. Yes.

Q. —are there any additional procedures that you do?

A. Absolutely. The placenta is usually still in the uterus, although occasionally it comes out first or during the procedure. I make a certain maneuver with the forceps to be able to remove the placenta as intact as possible.

Then, I use an instrument call a "curette." It is an instrument shaped like a long spoon that is introduced into [186] the uterus. It gently scrapes the walls

of the uterus to be sure that there aren't any little fetal parts or any parts of the placenta left behind.

And then, to complete the procedure, I use a suction cannula. It is like a large straw. It is attached to a suction machine, and it is used to just gently aspirate the uterine cavity.

Q. And how long does the entire surgical procedure take?

A. It really depends on how dilated the cervix is and how intact the fetus is as I extract the tissue. If the cervix is very well-dilated and the fetus comes down easily, then it can take just a matter of a few minutes. It can take as long as 10 to 15 minutes.

Q. Are there any advantages to doing the procedure more quickly?

A. Absolutely.

Q. What are they?

A. Well, assuming that the quick one is where the fetus is intact, then you don't have the sharp broken bones of the fetal body that are potentially able to lacerate the cervix as they are extracted, so there is a definite decreased risk to the mother then.

Also, the quicker the procedure, the smaller amount of bleeding that will occur. And then, thirdly, the anesthesia, the entire time that she's asleep under the |187| anesthesia she is at significant risks of aspirating. That is a condition where the stomach contents come back up into the throat, and then they are inhaled into the lungs. It is a life threatening condition. And our anesthesia people are constantly vigilant for such a situation. And being able to wake the patient up very quickly is definitely in her interest.

Q. Do you know when in the course of the D&E procedure that fetal demise occurs?

A. I don't know that.

Q. Do you pay attention to that?

A. I don't.

Q. Why not?

A. My goal is to complete the procedure as safely and quickly as possible, so I am not paying attention to it.

Q. How long have you been doing the D&E procedure in the manner that you just described?

A. I was taught during my residency in the '70's. And I have basically been performing it the same way in all those years, with some modification.

When I went to Planned Parenthood we focused a little bit more on the uniform preparation of the cervix and so that we would be sure we had adequate dilation at the time of the procedure.

Q. So the most significant change you have made to that procedure over the last 20 years is to the dilation aspects?

[188]

A. Correct.

Q. And how have you done that?

A. By consistently using the two days of preparation for the over 18 weeks.

Q. Dr. Sheehan, have you ever had a situation where the fetus comes out intact or partially intact?

A. Yes, I have.

Q. And how often does that occur?

A. It comes out partially intact very frequently; completely intact, less so. Just last week I was working with a resident from UCSD, and we had three of our 12 cases proceed so that the body of the fetus came out completely intact.

Q. Do you have a preference as to whether the fetus comes out intact or partially intact?

A. I definitely do. I prefer it come out intact.

Q. And when—what are the factors that influences that the fetus will come out intact or partially intact?

A. It is the relative sides of the fetus versus the relative aperture of the cervix that it has to come through.

Q. When a D&E results in an intact delivery, would you characterize that as a variant of a D&E, or a different kind of procedure altogether?

A. All the procedures that I am providing to get this request of the patient accomplished are, in my mind, the same procedure. I don't differentiate I am doing x, y or z [189] procedure. It is basically all under the termination to me of D&E.

Q. And are there any situations where you would expressly want to get an intact fetus?

A. There are.

Q. What are those?

A. I just had an example of this about two weeks ago. There was a young woman who came up from Mexico. Her fetal care had begun fairly late, and on an ultrasound it was identified that there were numerous fetal anomalies.

She decided not to take the time to have an amniocentesis, but to come directly to have a termination.

The doctor taking care of her had told her that these anomalies were not compatible with life, and so she was advised to come and have a termination.

In the same request, they wanted to have as much intact tissue as possible so that they could analyze the fetus after the termination procedure so that they would learn more about the condition of the fetus so that they could give advice to this young woman about her future pregnancies.

Q. Do you recall what type of fetus anomalies that fetus had?

A. I had multi cystic kidneys, abnormalities of the facial bones, and a cardiac malformation.

Q. Could you have done an induction under those circumstances?

A. An induction was offered to her. When we discuss options [190] with our patients, this is always an option offered to them. We don't actually provide induction, so if she had elected to do that, we would have referred her for that.

Q. She didn't pursue it. And why was that?

A. She was happy enough for us to tell her that we would do the best job we could to provide her with intact tissue, but we couldn't guarantee it.

Q. Are there any situations where an induction is contraindicated? Before we do that, can you explain for us what "contraindication" means?

A. "Contraindication" means when a procedure or a medicine is—carries more risk than benefit to the patient, so it is ill-advised.

Q. Do you have situations where and induction would be contraindicated?

A. Yes. Induction is usually carried out with prostaglandins. And if the woman has had one or more previous C-sections, the scar in the uterus is considered an area of weakness in the uterus and potential rupture, so women with previous C-sections are generally advised not to have induction.

Q. And are there any other situations you've had where a patient would want an intact fetus that you can think of?

A. It is generally for fetal anomaly diagnosis.

* * * * *

[193]

Q. Dr. Sheehan, do you as a physician have a preference as to whether the fetus emerges intact?

A. I do. I believe the procedure goes more quickly and more safely when the fetus comes out as intact as possible.

Q. Are there situations where you were doing a D&E and there was sufficient dilation to remove the fetus, except for the head?

A. Yes.

Q. And does it happen—how often does that happen?

A. That happens fairly frequently. In fact, I have been working with a resident from UCSD, as I alluded

earlier, and just last week three of our 12 procedures proceeded in this way.

Q. And why is it frequent that the fetus emerges except for the head?

A. The head is the largest part of the fetal body.

Q. And what do you do when that happens? What is your procedure?

A. Typically, I continue to put traction on the fetal body. If it is able to slide through the cervical aperture, then it will. That is rare.

Usually what happens is we need to disarticulate the fetal body at the neck, and then do a compression of the fetal head with a forceps to remove the head.

Q. And can you wait for the fetal head to deliver on its own?

[194]

A. That is not advisable.

Q. Why is that?

A. The patient is under anesthesia, and it would take quite a while for the uterus to labor enough to open the cervix further to allow the fetal head to deliver.

Q. Are there any special risks if the fetus emerges more intact than not?

A. I can't think of any.

Q. What is your overall experience with the safety of D&E? Do you have an opinion about the safety of D&E?

A. I think D&E's are very safe procedure. When discussing it with my patients, I always underline it is a

very safe procedure. It is at least as safe as going to term and delivering a baby. It is probably safer than appendectomy or tonsillectomy.

We actually have been tracking statistics at our Planned Parenthood affiliate for a number of years and have found that the number of complications in second-trimester abortions is actually less than the number in the first-trimester. So it is a very small percentage, less than 1 percent.

Q. And have you ever had a situation where you have had some complications as a result of the D&E?

A. Yes.

Q. What type of complications have you experienced?

[195]

A. We have had perforations and instances of hemorrhage and infection.

Q. And how often have you had a perforation during a D&E procedure?

A. The numbers in our affiliate are usually one or two perforations a year, and we are doing about 2,000 D&E's per year.

Q. So .1 percent, I think, if I do the math?

A. Correct.

Q. And were any of those situations where you were successful in removing the fetus intact?

A. No.

Q. Have you ever have had a retained placenta in performing a second-trimester D&E?

A. Never.

Q. So do you ever use a chemical agent to cause fetal demise?

A. Yes.

Q. What is that agent?

A. The agent is digoxin.

Q. What is digoxin?

A. Digoxin is the name for digitalis, which is a cardiac medicine that is typically used for specific cardiac conditions, most typically heart failure.

Q. And at what gestational age do you use digoxin?

A. We start using it at 22 weeks.

[196]

Q. Why do you choose 22 weeks?

A. We like to prevent an eventuality of a live birth, and because it seems to make the procedure move along a little bit easier on the day of the procedure.

Q. Are patients required to use digoxin at 22 weeks?

A. No. They are definitely given the choice.

Q. And are there any patients for whom you would not recommend digoxin starting at 22 weeks?

A. There is a group of heart conditions that are considered conduction defects, where the electrical conduction that pulses through the heart is abnormal.

A particular instance of that would be Wolff-Parkinson-White Syndrome where digoxin would be contraindicated, because it could potentially increase the dysfunction of the electrical conduction in the heart.

Q. Have you ever used digoxin before 22 weeks?

A. I have.

Q. And what are those circumstances?

A. It has been in a situation where the patient actually requested it.

Q. But you don't generally use it before 22 weeks; is that right?

A. No, I don't.

Q. And why is that?

A. It would be an additional unnecessary procedure that would [197] potentially add risk to the procedure.

Q. And what kind of risks are there?

A. Risk of infection or risk of going into labor early.

Q. Have you ever seen a woman who became infected as a result of a digoxin injection?

A. I have.

Q. Can you describe that for us?

A. I have seen one patient that I am fairly certain had infection. She had what is described as chorioamnionitis, which is generalized infection of the membranes inside the uterus around the fetus.

In another case where I was suspicious that she was infected because of the administration of digoxin, mainly because she had a fever.

Q. And you indicated digoxin causes fetal demise; is that right?

A. Correct.

Q. Does it cause it in every single time it is administered?

A. No, it is not 100 percent uniformly successful.

Q. And why is that? Do you have any sense of why it is not uniformly successful?

A. We administer the digoxin with a needle through the abdominal wall of the woman into the uterus. We are aiming to get it into the fetal heart, or at least into the fetal thorax. However, we are not able to do that every time. If we are not [198] able to do that, then we attempt to put the digoxin into the amniotic fluid. And it seems to work less often when it is just put into the amniotic fluid.

Q. What percentage of time are you successful in getting the digoxin into the fetal heart?

A. I would say approximately 50 percent.

Q. And when do you administer—when do you administer the digoxin when you use it?

A. The day before the procedure.

Q. And why do you do it then?

A. We started doing it on the first day of laminaria, and we found too many women were going into labor early.

Q. So you now do it 24 hours in advance of the actual procedure?

A. Correct.

Q. Do you know when it takes effect?

A. I have not looked at that.

Q. Have you ever used a chemical agent called "KCl," or "potassium chloride" in the context of the D&E procedure?

A. No.

Q. So, let's see.

MS. PARKER: May I approach just for collection of the—

BY MS. PARKER:

[199]

Q. Dr. Sheehan, at the beginning of our testimony yesterday you indicated you were going to testify also about the partial-birth abortion ban act and the impact in your practice. Do you remember that?

A. Yes.

Q. And I've put up here a section of that act. Do you see that?

A. I do.

Q. And have you seen that before?

A. Yes.

Q. When did you see it?

A. When the act was passed.

Q. Are you concerned about the potential impact of this law on your practice as you've described it this morning?

A. I am very concerned.

Q. Why are you very concerned?

A. Because as I've discussed, it is frequent and preferred that I do something that is described in this act, which is that the fetus is delivered, in the case of a breech presentation, to the—any part of the fetal trunk is past the navel. So I am afraid that what I do meets the description here in the act.

Q. And in addition to the impact on your own practice, do you have other concerns about the impact of the act?

A. I am very concerned. I have heard a number of providers [200] discussing that they would find it difficult to continue providing second-trimester abortion care if this act actually went into effect.

Q. And would that create any problems if people cease doing second-trimester abortion care?

A. Absolutely. It would make it more difficult for women who are seeking these procedures to actually get them. There probably would be a delay in accessing the care.

And we know that every week that a woman waits further into gestation, her risk of complication goes up by 50 percent. So it is essential that women seek the care as soon as possible.

Q. And why exactly would this act impact on your practice, on how you perform your procedures?

A. Well, I would be concerned about the attention that I have been placing on obtaining excellent cervical dilation, because that part of the process which I believe creates the safety of the procedure would be also putting me in the position of violating the act.

So I would feel like I would have to consider not dilating as far, which would not be preferable, because that is the safety—the safety feature of my procedure.

Q. And do you know what the term "deliberately and intentionally" means?

A. I don't understand it. I know a little bit of grammar, and [201] I know those are adverbs, and they

should be modifying the verb, which is "delivers." So "deliberately and intentionally delivering," that is what I do. That is what I am trying to do in my procedure.

Q. And what about the term 'living fetus," what does that mean to you?

A. It would be a fetus that still has a heartbeat, and that would still apply to many of my cases.

Q. And in your practice do you bring the fetus to the point where the fetal trunk past the navel is outside the body of the woman?

A. Yes, I do. That's what I mainly do.

Q. And that happens often?

A. Yes.

Q. And you have a preference for that?

A. I do.

Q. In your opinion, could this law be understood as violating D&E's for disarticulation occurs?

A. Yes, that is possible.

Q. And how would that happen?

A. If a disarticulation procedure had started, but the fetus then was delivered to the level of the navel, it could still be living. The heartbeat could still be going, and the fetus would have already had a disarticulation procedure started.

Q. And have you encountered those situations in your practice?

|202|

A. Yes.

Q. Do you know what the term "overt act" means?

A. Not really.

Q. Now, you understand that there has been an injunction entered in this case, and right now the act is not being enforced; is that right?

A. Yes.

Q. If the injunction were lifted, do you know what you would do with your practice?

A. I would have to consider long and hard how we are providing D&E's. The evolution of the process that we are doing now has been based on trying to achieve the highest safety for our patients, so we would have to consider each part of the preparation and the procedure to try to avoid violating the ban.

MS. PARKER: May I also get another?

THE COURT: Yes.

BY MS. PARKER:

Q. So, Dr. Sheehan, I would like to show you another portion of the Partial-Birth Abortion Ban Act, which is known as the "Civil Action Provisions." Do you see that which is before you?

A. I do.

Q. Have you seen that before?

A. I have.

[203]

Q. And that provision states that if the father is married to the mother at the time she receives a partial-birth abortion procedure, and if the mother has not attained the age of 18 years at the time of the abortion, the maternal grandparents of the fetus may, in a civil action, obtain appropriate relief, unless the

pregnancy resulted from the plaintiff's criminal conduct or the plaintiff consented to the abortion.

Do you see that?

A. Yes.

Q. And that indicates essentially that if the father or maternal grandparents of the fetus could sue, right, if they don't give consent to the procedure?

A. Yes.

Q. Do you currently obtain consent for the abortion from the father?

MR. SIMPSON: Your Honor, I am afraid we have to object to this line of questioning. I don't believe that there is any allegation in the complaint regarding this provision.

THE COURT: And so your objection is irrelevant?

MR. SIMPSON: Exactly.

THE COURT: Okay.

MS. PARKER: But this goes to the impact of the act if it is not enjoined on her practice.

THE COURT: I actually want to hear from all of the positions by both sides about their opinion as to the impact. [204] I will permit this line of questioning.

And you may ask your experts the same questions, if you wish to do it.

BY MS. PARKER:

Q. Dr. Sheehan, do you currently obtain consent for the abortion from the father?

A. I don't. The decision to obtain an abortion is a very private matter between the patient and me, her physician. So I don't ask the permission of anybody else.

Q. And do you ever obtain permission from the maternal grandparents of the fetus if the mother is not yet 18?

A. That would be my patient's parents, and, no, I don't ask their permission.

Q. And if the act went into effect would you have to change your practice in that regard in terms of the consent you obtain for the procedure?

A. I would.

Q. Are you concerned about that?

A. I am very concerned about that. I see patients in a number of situations where this would really cause a significant disruption in the relationship between the patient. And the women who come in for second-trimester procedures particularly are in some sort of chaotic situation in their lives.

Frequently maybe their husband is just leaving them. They are not in good relationships with their families. And to [205] have to obtain the consent of somebody who is not looking out for the patient's best interest would definitely cause a problem.

MS. PARKER: Thank you, Dr. Sheehan. I have no further questions at this time.

THE COURT: I just have a few questions before you start question, counsel.

With regard to the procedure that you use when the fetus is delivered pretty much intact and the head is

lodged, is the procedure that you describe, the disarticulation of the neck, the only procedure that you use in that scenario?

THE WITNESS: It is not the only procedure. If the cervix is adequately dilated and effaced so it is thin, I can sometimes get one of the forceps around the fetal head to compress it without actually disarticulating.

THE COURT: Okay. And is the preparation of the cervix the same regardless of whether or not the procedure is a D&E or intact D&E?

THE WITNESS: I don't differentiate those two procedures. I set out to do a D&E to obtain the termination of the pregnancy of the patient, so I don't really consider my self doing intact D&E. If that happens as part of the process, then I'm actually relieved, because it reduces the risk for the patient.

But, it's all part of the same continuum to me.

[206]

THE COURT: All right. So is it appropriate for me to assume, then, from your testimony that you have no control over whether or not the extraction is going to be intact or partial?

THE WITNESS: You're exactly right. This is something that happens as we evaluate the cervix at the beginning of the procedure. The woman has already gone through two days of preparation of the cervix. It is not until that moment when she is already lying on the table and asleep when I am able to evaluate what the dilation of the cervix is.

So it is at that moment that I am able to have more information and can make a judgment about how the procedure is going to proceed at that point.

* * * * *

[KATHERINE SHEEHAN, M.D. - CROSS EXAMINATION]

[231]

Q. That was not my question. Is it true, doctor, we have talked about when the physician is attempting disarticulation, I have asked you whether there are certain maneuvers that the physician uses with the forceps to do that.

Now, I am asking about the other side of it. When the physician is attempting to remove the fetus intact, are there certain distinct maneuvers that the physician uses?

A. They are basically the same maneuvers, as long as the fetal parts are low and you are attempting to reach those.

Q. If I could have you turn to your deposition, doctor. The whole part, the main part, not the confidential part. Page 101, please.

If I could ask you to read, doctor, to yourself page 101, line 22 through page 102, line 8.

Have you read that?

A. Uh-huh.

Q. Thank you.

If I could read that to you, page 101, starting on line 22.

And I should say first this question refers to your expert report; is that correct?

A. Uh-huh.

Q. "Question: Could you describe, doctor, what you mean in paragraph 4 by your 'best efforts to remove the fetus intact'?

[232]

"Answer: I think I already described that, but what I attempt to do is to grasp the fetal feet with the instrument, and putting gentle traction on that fetal extremity, I try to tease the tissue down so that the fetus comes down feet first through the cervix, the pelvis and the thorax, and I actually get the arms out and just use gentle traction, rather than using the kind of crushing and compressing gestures that one would use to do the disarticulation."

Is that what you said?

A. Yes.

Q. Isn't it true, doctor, that when you were observing the other physician do the abortion that we discussed during the confidential portion of your deposition, isn't it true that you could observe that she was attempting disarticulation because she was using the crushing and compressing gestures that you referred to in what we just read?

A. What she was trying to do was make contact with the fetus. She had not successfully done that. She was exploring the uterus with her forceps to attempt to make contact with the fetus, and to bring it down.

Q. Doctor, it appears that your testimony during the confidential portion of your deposition is inconsistent with what you are saying now. You said during that confidential [233] portion:

> "Question: You told me that you know the physician was not attempting to turn the lie of the fetus. How do you know that they were not trying to do this?
>
> "Answer: Because the physician was disarticulating and attempting disarticulation.
>
> "Question: But she did not succeed in doing that?
>
> "Answer: Correct.
>
> "Question: How do you know that she was attempting disarticulation?
>
> "Answer: Because I could observe her maneuvers with the forceps."

You are telling us now that there are no such gestures.

A. I think the distinction is that she—the difference of what she was doing was introducing the forceps, opening them wide, compressing, and trying to bring down the fetal part so she could start the procedure.

The procedure that we use is generally disarticulation and crushing maneuvers to get the fetus small enough to fit through the aperture.

I was training this person. I knew exactly what her maneuvers were trying to do. She was not reaching up inside the uterus to try to get the fetal feet that were at the top of [234] the uterus and reverse the lie of the uterus.

She was just trying to get—grab onto the fetus and bring it down.

Q. Back to your testimony on page 2 of your deposition, you would agree now that there are crushing and compressing gestures that one would use to do the disarticulation of a fetus?

A. It's basically the same: you close—you open and close the forceps. And if you open and close it on a fetal part and with traction, the whole fetus comes down, that is good. If you open and close it and there is too much traction against the cervix so that it disarticulates, then you get disarticulation.

Q. And you would agree with your prior testimony, I assume, that when you are attempting to remove the fetus intact, you use gentle traction to try to tease the tissue down?

A. It's still the same basic maneuver: You put—you open the forceps. You close it on the fetal part, and you bring it down.

Q. Your testimony in the deposition was truthful?

A. Yes.

Q. Doctor, do you know—do you recollect in the case that we discussed in the confidential portion of your deposition, do you recollect approximately the gestational age of that fetus?

A. I believe it was 23 weeks.

* * * * *

[235]

Q. I think you've testified, doctor, that you sometimes have to compress the fetal skull to complete the removal of the fetus?

A. Correct.

Q. Your purpose in compressing the skull is not necessarily to cause fetal demise?

A. No.

* * * * *

[236]

Q. Using ultrasound reduces the risk of leaving fetal parts inside the uterus?

A. Yes.

Q. The use of ultrasound also reduces the risk of unintentionally injuring the patient with your instruments?

A. Yes.

Q. In approximately what percentage of your second-trimester surgical abortions have you unintentionally injured the patient with an instrument?

A. I can tell you that personally less than 0.1 percent of the time.

Q. This is a remarkably small percentage, correct?

A. Yes, it is.

Q. You also believe that the use of ultrasound decreases the number of times that you have to reach in into the cervix to get a fetal part?

A. It does help you direct the forceps.

Q. It reduces the number of times that you have to reach in with the forceps?

A. It probably does. It is not certain that it does.

Q. Doctor, I think you've testified that in your opinion the intact removal of the fetus in a second-trimester

abortion is safer for the woman than removal by dismemberment?

A. Yes.

Q. Can you identify, doctor, for us which risks of D&E that * * *.

* * * * *

[243]

Q. What percentage of patients accept that offer?

A. All of them.

Q. Do you know whether other Planned Parenthood affiliates offer digoxin before D&E?

A. They do.

Q. How many?

A. I know of one.

Q. Which one is that?

A. Los Angeles.

Q. Do you know of any others?

A. No.

Q. Do you know at what point Planned Parenthood Los Angeles offers an injection of digoxin? At what point of gestational age they offer that?

A. I believe they start at 21 weeks.

Q. In your experience, doctor, does causing fetal demise before starting the removal in a D&E make the removal easier?

A. In my experience it does make it easier.

Q. That is because the fetus is easier to dismemberment?

A. The fetal tissue is softer.

Q. And it is easier to disarticulate?

A. Yes.

Q. And does it also make the head easier to compress?

A. Yes.

Q. In your experience, doctor, digoxin injection is * * *.

* * * * *

[247]

A. Yes.

Q. Are you familiar, doctor, with the procedure known as amniocentesis?

A. Yes.

Q. Now, is it true, doctor, that a physician who has the skill to perform an amniocentesis would also have the skill to perform an injection of digoxin for fetal demise?

A. Yes.

Q. Every OB/GYN learns how to do an amniocentesis?

Q. Correct.

A. Continuing there in Exhibit A-48, second paragraph, second sentence:

> "However, possible complications include, but are not limited to, infection, shock, allergic reaction and even death."

You've seen two cases of infection after a digoxin injection; is that correct?

A. These cases that I assume are related to digoxin injection, yes.

Q. You just assumed that, but it was never shown definitively that the infections were caused by the injection?

A. Correct.

Q. You started using digoxin to cause fetal demise in the year 2000?

A. Correct.

[248]

Q. And you do about 100 per year?

A. That's correct.

Q. And in those two cases that you referred to, no longer term effects occurred in either of those two cases because of the infection?

A. That's correct.

Q. And you don't know of any cases of infection that were actually shown to have been caused by a digoxin injection?

A. Correct.

Q. If any such infection occurred, doctor, emptying the uterus in the course of the abortion would reduce the risk of any long-term effects of an infection?

A. Yes.

Q. The sentence that I just read from Exhibit A-48 lists some other potential complications:

"Shock, allergic reaction and even death."

Now, you have never heard of any occurrence of any of those complications?

A. Correct.

Q. You've never experienced any of them in your practice?

A. Correct.

Q. Doctor, I would like to show you plaintiff's Exhibit 31 in this case. Are you familiar with that book?

A. I am.

MR. SIMPSON: Does the court have a copy of that?

* * * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

TRANSCRIPT OF TRIAL PROCEEDINGS
Tuesday, Mar. 30, 2004
Volume 2

BEFORE THE HONORABLE
PHYLLIS J. HAMILTON, JUDGE

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* * * * *

[ELEANOR DREY, M.D. – DIRECT EXAMINATION]

[274]

* * * * *

Q. Dr. Drey, you are a physician at San Francisco General Hospital; isn't that right?

A. Yes.

Q. What is your area of medical specialty?

A. Obstetrics and gynecology.

[275]

Q. Is it all right if I refer to San Francisco General Hospital as SFGH?

A. Yes.

Q. What is your title at SFGH?

A. I am the Medical Director of the Women's Option Center.

Q. Aside from being Medical Director of the Women's Option Center, what other professional activities are you involved in?

A. I'm a generalist obstetrician, gynecologist, so as that, I work as an attendant. So I attend inpatient and outpatient obstetrics and gynecology.

Q. Any other professional activities?

A. I teach residents and medical students and fellows.

Q. And is that through SFGH or some other entity?

A. That's through the UCSF.

Q. I would like to talk to you about the Women's Option Center.

What is the basic mission of the Women's Option Center?

A. It's to provide excellent clinical care and abortion and in contraception. Our mission is also to perform research and abortion care and to train future abortion providers.

Q. And specifically what services does the Women's Option Center provide?

A. We provide options counseling, contraception counseling and provision, abortion counseling and provision, and pregnancy [276] testing.

Q. Generally speaking, to whom does the Women's Option Center provide this kind of care?

A. We have a very mixed population. It's predominantly lower income women, but we also serve high risk medically-complicated patients.

Q. And do you serve patients just from the San Francisco geographic area or is it broader than that?

A. No, actually our patients are drawn from sort of all Northern California and sometimes others states and other countries.

So, we actually serve a large geographic region.

Q. You had mentioned a moment ago that you have a good number of medically complex cases that are referred to you.

Why are medically complex cases referred to the Women's Option Center? Is there anything special about it that specifically—that's specially equips it to handle greater health risks?

A. Well, we are located in a general trauma center and a general hospital. So, as such, we have facilities so that should a woman have a complication in that case, then we would be able to help her.

Q. Now, you testified that you are the Medical Director. What does that job involve?

A. It involves making sure that we provide excellent abortion [277] and contraception care, so overseeing the activities of the clinic primarily.

Q. Do you perform abortions?

A. Yes.

Q. Do you supervise abortions?

A. Yes.

Q. Do you establish protocols for the Women's Option Center?

A. Yes.

Q. Do you supervise any employees at the Women's Option Center?

A. Yes.

Q. Who do you supervise?

A. I am the direct supervisor for the head nurse, the head counselor and one research assistant, but then I generally supervise everyone in my role as Medical Director.

Q. You mentioned teaching earlier, teaching medical students and residents. Does part of that teaching occur at the Women's Option Center?

A. Yes.

Q. Do you do any administrative work in connection with your role?

A. Yes.

Q. Can you describe what you do?

A. I—well, in addition to the functions that I described, I work with the administration of the hospital to ensure that we [278] can continue to provide safe abortion and contraception services.

Q. I would like to turn specifically to the provision of abortions at the Women's Option Center. Does the center provide women with D&E's?

A. Yes.

Q. Up to what gestational age are D&E's performed?

A. We do D&E's until 23 weeks one day or biparietal diameter 56 millimeters.

Q. Now, you say 23 weeks one day is equivalent to biparietal diameter of 56 millimeters. Yesterday, Dr. Sheehan testified that in her practice she does abortions to 24 weeks, which is—which she described as 56 millimeters biparietal—by BPD.

Can you explain the discrepancy between your testimony and Dr. Sheehan's testimony in that regard?

A. Yes. I think those of us who use ultrasound determination of gestational age do so based on the growth charts that are actually programmed into the computer.

So if you had a measurement of a certain number of millimeters based on that growth chart on the ultrasound, you will either get a measurement at 56 millimeters according to one computer, one ultrasound growth chart will be 23 weeks one day another growth chart—sorry. I'm speaking too fast.

THE REPORTER: I'm sorry, 23—

[279]

THE WITNESS: A growth chart that in one ultrasound at a BPD of 56 millimeters is read as 23 weeks one day and another ultrasound will read the same measurement as 24 weeks.

BY MS. MORRIS:

Q. Are you saying that what really matters is the size of the BPD?

A. That ultimately is what we are all concerned about is the size of the fetus and specifically the size of the calvarium.

Q. And why is 56 millimeters the cutoff at the Women's Option Center?

A. That decision was made in reference to considerations of both the technical difficulty of the procedures that we would be performing, but also in regards to limits on viability.

Q. Does the Women's Option Center offer abortion methods other than D&E?

A. We do.

Q. Can you tell me what they are?

A. We also do suction abortions, medical abortions, and induction abortions.

Q. How many physicians provide abortions at the Women's Option Center?

A. We have 16 attending physicians and they supervise a varying number of residents. So those are resident physicians who also provide abortions for first-trimester abortions. They also supervise medical students who provide some of the [280] first-trimester abortions, but not the second-trimester abortions.

Q. How many abortions does the center provide a year on average?

A. Approximately 2,000.

Q. And of those 2,000 what percentage are second-trimester abortions?

A. Slightly over half.

Q. And of the second-trimester abortions, what percentage are performed at 20 weeks or later?

A. Approximately 60 percent.

Q. Why does the Women's Option Center have such a high percentage of patients at 20 weeks or later?

A. It really has to do with the population that we see our responsibility to serve, and that population is poor women. In California—as well as medically-complicated women.

So we, preferentially, women at later gestations who have medical complications are referred to us because we are seen as experts in the provision of late second-trimester abortion.

But in addition to that, we see, as part of our mission, serving the poor women of Northern California and really they have nowhere else to go. There is only one other clinic who can accept all types of medical or the state insurance for these abortions at 20 weeks and above, and they [281] do—they can only accept very few of these because they reimburse very little.

So, essentially, we end up taking care of all of the poor women who need abortions at 20 weeks and above for all of Northern California.

Q. I would like to talk about the Partial-Birth Abortion Ban Act of 2003, which I will call the Act.

Have you read the Act?

A. Yes.

Q. We have a portion of the Act blown up which I will—with permission?

THE COURT: Yes.

BY MS. MORRIS:

Q. Would you please take a moment to read that, again?

Do the physicians at the Women's Option Center perform abortions that fall within the definition of partial-birth abortion in the Act as you read it there?

A. Yes.

Q. Do you yourself perform abortions that fall within this definition?

A. Yes.

Q. Could you please explain what you mean by that?

A. Our—the type of abortions we provide in the second-trimester largely is D&E, but any time you do a D&E abortion, depending on the degree of cervical dilation that you [282] have achieved, then it's possible by grasping fetal parts to deliver the fetus beyond the navel, and then to have to continue the procedure and violate the act.

Q. Do you have any control over when fetal death occurs in the course of that proceeding?

A. Well, I mean you don't have any control over—I mean, what you are really paying attention to is trying to complete the abortion safely. So, what you are mainly trying to do is extract the part safely. So, not exactly.

Q. You are aware, are you not, that there is an injunction in this case that protects the physicians at SFGH from being criminally prosecuted under the Act?

A. Yes.

Q. If that injunction were lifted and the Act went into full effect, what impact would it have on physicians at the Women's Option Center?

A. I think it would have a large impact on our physicians. I think that it would be very difficult for us to continue to provide second-trimester abortions because of this Act.

Q. Can you say more about the effect the Act would have on your ability to perform those abortions?

A. I think that because any kind of—any D&E that we do could end up falling under that definition, the physicians would be concerned that they would be violating this act and, therefore, the physicians with whom I work would no longer feel [283] comfortable performing D&E's.

And, in fact, I already made some changes in the clinic just because of concerns about the Act.

Q. Can you give me some examples of changes that you've made?

A. Well, we usually, we used to really counsel all patients about welcoming someone to come in the procedure with them to serve as a support person, whether that be a family member or parent, a friend, or someone who could come in the room with them.

Because of this act, I was concerned that in the later procedures those people might misinterpret what was happening, and so I no longer encourage the counselors to bring this up.

If a patient requests for a support person to be with them, we don't absolutely restrict it, but we no longer offer it sort of part of our routine counseling like we used to.

I also felt that instead of allowing medical students to observe all of the procedures that we do, I would no longer encourage them to see the later procedures, again, because I was concerned that they might interpret something that we were doing as violating the Act and I didn't want to cause that concern among our staff.

Q. Other than the impacts that you have already talked about, what other impacts would the act have on the Women's Option [284] Center if it were enforced?

A. I don't think we have enough physicians to perform second-trimester abortions, and I think what would end up happening is that poor women would have nowhere to go in Northern California, nor would women with medical complications that might make a D&E more difficult because a huge number, I don't know if all of them, but we get most women as far as I know who have really acute medical or risky surgical issues.

Q. Can you state broadly what impact you think the Act would have on the availability of abortion services in Northern California generally?

A. I think that if you were—well, I was going to say if you were insured you might have somewhere to go, but I think that many providers—in fact, I have had providers call me and say that they no longer are sure whether they should do second-trimester abortions because they don't know if they would be violating this Act.

So, I was going to say that if you had insurance, you might still be able to find a provider. If you don't have insurance or if you have Medi-Cal, you might not be able to find a provider in Northern California who

could provide these services. So I am concerned that women would have nowhere to go to get a second-trimester abortion.

MR. SIMPSON: Your Honor, we must object. I think we're moving into the area of speculation, and we object and [285] ask that the answer be stricken.

THE COURT: I am not going to strike the answer, but I tend to agree that some of it is a bit speculative. I am not going to strike it.

Perhaps you can move on to another area.

MS. MORRIS: Yes, thank you, your Honor.

BY MS. MORRIS:

Q. Just one last topic.

You had mentioned earlier that you get a disproportionate number of women coming to the Women's Option Center who have medical complications or just medically complex cases.

Can you give me some examples of cases like that?

A. We generally get referred women who have had multiple or even one cesarean section in the past, women who are morbidly obese, women who have limited intravenous access, women with placenta previa, women who have severe medical conditions among other complications.

Q. Again, they are referred to you because?

A. Because of our being a trauma hospital, we are able to help them where a free-standing clinic might not feel comfortable to do their abortion because we are seen as the safest place to do abortions for these women.

MS. MORRIS: Thank you. I have no further questions.

[286]

THE COURT: As I recall yesterday, you advised that you were splitting up the examination.

MS. MORRIS: Yes.

THE COURT: So Planned Parenthood counsel wishes to examine Dr. Drey further?

MS. PARKER: Yes, your Honor.

The reason is she is a percipient witness for the City and she's our expert.

[DIRECT EXAMINATION]

BY MS. PARKER:

Q. Good morning, Dr. Drey.

How are you doing?

A. Okay.

Q. I am Beth Parker, attorney for Planned Parenthood.

Dr. Drey, have you also come here prepared to state your opinion as to the safety and efficacy of administering digoxin to cause fetal demise before termination of a second-trimester abortion?

A. Yes.

Q. And before we go into your opinions, I just wanted to ask you a few more background questions.

In addition to serving as the Medical Director of the Women's Options Center, I believe you also indicated that you do some teaching; is that right?

A. Yes, I do.

[287]

Q. And where do you do that teaching?

A. I largely do it at the University of California San Francisco. So that's both at the medical school and at the hospital as one of its sites, but I also teach at other universities.

Q. Do you have a title at UCSF? Can we call University at California San Francisco UCSF?

A. I'm an Assistant Clinical Professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences is my title.

Q. What are your responsibilities as an Assistant Clinical Professor?

A. It is to teach residents, medical students, and fellows as well as to do clinical care and do research.

Q. Do you teach any methods of abortion?

A. I do.

Q. And what are those methods?

A. I teach first-trimester and second-trimester surgical abortions. So, that would be suction abortion in the first-trimester and D&E in the second-trimester.

We also teach induction termination and medical abortion in the first-trimester.

Q. What do you mean by "medical abortion in the first-trimester"?

A. That largely is using the mifepristone, misoprostol and in the first-trimester.

[288]

Q. Do you also do research?

A. Yes.

Q. In what areas?

A. Largely on contraception and abortion.

Q. Do you have any special training that qualifies you to teach in this area and do research in this area?

A. I did a clinical and research fellowship in family planning.

Q. When did you do that?

A. I did that from 2000 to 2002.

Q. Where?

A. At UCSF.

Q. Do you have any ongoing role in that fellowship program?

A. I continue to teach the fellows in that program and assist them with their research.

MS. PARKER: May I approach the witness, your Honor?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Drey, I have shown you what has been marked as Exhibit 33.

Do you see that?

A. Yes.

Q. Is that your C.V.?

A. Yes.

Q. Did you prepare it?

[289]

A. Yes.

Q. Is it basically—is it true and correct or accurate?

A. Yes.

THE COURT: Is it basically?

MS. PARKER: Not basically.

BY MS. PARKER:

Q. Is it accurate?

A. It is accurate. But, you know, as time passes, you are supposed to keep it up to date. So I haven't made any minor additions since then.

MS. PARKER: I would like to offer Exhibit 33 into evidence.

MR. SIMPSON: No objection.

THE COURT: Admitted.

THE CLERK: 33 into evidence.

(PLAINTIFF'S EXHIBIT 33 RECEIVED IN EVIDENCE)

BY MS. PARKER:

Q. Dr. Drey, have you served as an expert witness before in a case involving the provision of abortion services?

A. No.

Q. Have you served as an expert witness before?

A. No.

Q. Are you being compensated for providing expert testimony in this case?

[290]

A. No.

MS. PARKER: I would like to move to qualify Dr. Drey as an expert witness in the areas of obstetrics and gynecology in the provision of abortion.

THE COURT: Any objection?

MR. SIMPSON: Your Honor, I am afraid we do have to object to the breadth of that statement. Dr. Drey's expert report was very much limited to the intrauterine injection of digoxin to cause fetal demise.

During her deposition we asked her a long series of questions as to whether she's offering testimony at trial regarding other things. I can read that series to the court.

MS. PARKER: We don't plan to go beyond the digoxin area, but I do think she qualifies as an expert in these areas, which is why I moved her.

THE COURT: I don't know it is necessary on this particular subject to parse out her qualifications so minutely as to limit her to that one area. She clearly has expertise in her role in more than just the area of the use of digoxin.

So, I understand it's broader than most of the offers have been, and perhaps you can narrow it in some way, but I don't—those are two separate issues what she is going to testify on today is separate from the breadth of her qualifications. She is clearly, and I believe you all have stipulated to the basic qualifications of all the medical [291] providers who have medical degrees and some degree of experience in OB/GYN. So she's, in other words, I am going to overrule your objection.

BY MS. PARKER:

Q. Dr. Drey, you have told us that you are prepared to state your expert opinion on the safety and efficacy of the use of digoxin in the second-trimester abortion; is that right?

A. Yes.

Q. What is that opinion?

A. My opinion is that although digoxin is safe in most cases, that that does not necessarily mean that digoxin is safe in every case; that there's some women in whom—and that even though digoxin is safe, that we have not really demonstrated that it is actually effective in making D&E procedures safer.

There are also women in whom digoxin cannot be used because it is contraindicated. Digoxin does not work all the time in order to cause fetal demise. Digoxin technically cannot be administered in some women due to their obesity, and that's all I can think of right now.

Q. Okay.

And now you have provided us with several sort of aspects of that opinion. What are the bases for these opinions about the use of digoxin?

A. The bases are the research studies in which I participated and my clinical experience.

[292]

Q. And what were those research studies?

A. We did a study on the safety of intra-amniotic digoxin and a study on the efficacy of intra-amniotic digoxin.

Q. Would you just describe for us what a safety study is?

A. A safety study, often you will hear talked about as a phase I clinical trial. It's when you have a nonrandomized small group of patients in whom you administer a certain intervention and then you make sure that that intervention is safe. Usually that's a drug.

Q. What is an efficacy study?

A. An efficacy study is where you ideally randomize two groups of—well, usually two groups of subjects to either get the intervention or not to get the intervention, and then you actually see whether the intervention had the intended effect of improving the health or the procedure that you are evaluating.

Q. So you did both a safety and an efficacy study on the use of digoxin?

A. Yes.

Q. When did you do the safety study?

A. The safety study was done in 1998.

Q. When was the efficacy study done?

A. In 1999 to 2000.

Q. Why did you do them?

A. Well, we did them because, as you've heard testify to, [293] digoxin is really used widely in the community of physicians who provide abortions because those physicians—well, they use it for a number of reasons, but I think in part they use it because they believe that the abortion will be safer if they use digoxin.

So, we wanted to study that. That seemed an important question because you don't want to do un-

necessary or potentially dangerous interventions if you don't know that they actually work just based on, you know, clinical experience.

But in order to do an efficacy study, you really ethically need to make sure that the intervention is safe. So before we could do the efficacy study we did a safety study first.

Q. Before we get into the details of the studies I just want to understand your role in the two of them. What was your role in the safety study?

A. My role in the safety study was to help design it, administer it and analyze the results. And then, I was —I wrote up that study.

Q. You were the primary author of the study?

A. Yeah, I was the lead author.

Q. And what about the efficacy study? What was your role in that one?

A. Again, I helped design the study, administer and supervise the study, and helped in the analysis and some of the writing.

* * * * *

[307]

Q. You indicate you recruited patients for the study. How many did you recruit?

A. We recruited eight.

Q. Why did you select only eight?

A. In designing the study we worked with one of the authors, Dr. Benowitz, who is an expert in design of safety studies.

He is both a pharmacologist and an internal medicine physician. And he felt that eight was an adequate number to determine the safety of intervention.

Q. Did you have any exclusion criteria or did you exclude any types of patients from your safety study?

A. We had a series of excluding criteria.

Q. What were they?

A. Women had to be at least 18 years old.

They had to be able to consent to the study.

They had to have fetal cardiac activity. And then, they would be excluded if they had significant medical illnesses, cardiovascular disease, if they were using cardiac or antihypertensive medications, if they were allergic to digoxin, if they had pregnancy complications, and if they had maternal weight greater than 30 percent above ideal body weight, and if they had poor venous access or abnormal potassium levels.

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[308]

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Q. Hi, Dr. Drey. Before the break, we were talking about the exclusion criteria that you used for the safety study you used on the use of digoxin, and you listed a number of exclusion criteria. I want to ask you a few questions about some of them, if I could.

A. Okay.

Q. One of them, as I recall, you excluded women with significant cardiovascular disease?

A. Yes, we didn't want—since it was a safety study involving a small number of patients, we didn't want to

put—potentially put any women who had cardiovascular disease at any unintended risk.

Q. And why was that? Did it have anything to do with the digoxin, in particular?

A. Yes, because digoxin is a cardiac medication.

Q. I think you also indicated you excluded women with [309] pregnancy complications?

A. We did.

Q. And why was that?

A. Primarily, again, because the study wasn't really looking at how digoxin might be safe in the case of pregnancy complications. And, in particular, the pregnancy complications of having either too much amniotic fluid or too little amniotic fluid might change the results that we would see.

Q. Another exclusion criteria was women who were more than 30 percent over ideal weight?

A. That has to do with the fact that, well, there is more there there. So I think if you have a larger subject you would expect the results potentially to be different based on that.

So if we were trying to see how safe it was for the average person, and given that we were only going to involve eight subjects, we didn't want to change the results by involving women who were very obese.

Q. Was there any other aspect of—for very overly obese women that caused you to exclude them from the study?

A. It's technically difficult to do—somebody take my beeper. Sorry.

It technically can be difficult to do intra-amnoitic injection if someone is morbidly obese.

Q. And why is that?

A. Again, there is more there. I mean, so you are using a [310] needle of a given length, and you have to get through the abdominal wall, and then, in turn, through the uterine wall to get into the place where you need to inject the medicine.

So it is just not easy sometimes if someone has a lot of weight in front.

Q. Were any women actually excluded from your safety study?

A. Yes, we did exclude some subjects.

Q. Do you recall what the reasons were for the actual exclusions?

A. Two subjects were excluded because they had low potassium levels, and one subject was ex—those were the two—those were the two I remember.

Q. The too high potassium levels?

A. Low potassium levels.

Q. Low potassium. And why were they excluded?

A. Because we didn't want to potentially have any arrhythmia associated with the digoxin or affect the results that we would see.

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[320]

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Q. You indicated there were 126 women who were enrolled in the study. And what type of women were they?

A. These were women who were sure that they were going to have an abortion. They were able to consent. They spoke either English or Spanish. And then, we had, again, very similar exclusion criteria from the safety study.

Q. Did they fall within a certain gestational age?

A. Yes, they were all between 20 and 23 weeks, one day.

Q. And you indicated the exclusion criteria were essentially the same as the exclusion criteria for the safety study?

A. Very similar.

Q. Did you end up excluding any women from participating?

A. Some women who were not English or Spanish speakers were excluded. There was a patient who was in prison and therefore unable to consent fairly.

There were patients who had obstetric complications, and then there were women who were excluded for contraindications to digoxin. And one of those women had renal failure and another had uncontrolled hyperthyroidism.

[321]

Q. Do you recall what the pregnancy complication was that caused the exclusion?

A. I believe that they had multiple gestations. That means like twin or triplet gestations.

And then there were women who wanted to be —intended to be randomized, but one woman changed her mind and decided not to have the abortion. And then, another woman, her amniotic—her water broke when we were putting in the dilators.

Q. So how was the study then conducted?

A. So, the subjects, as I said, they received the usual evaluation. Then, they had the dilators placed. They had the digoxin injected intra-amniotically. That was not done under ultrasonic guidance, but correct placement of the needle was assessed, as I described, looking for the amniotic fluid to come up through the needle.

And then, the either 1 milligram of digoxin or the placebo was injected. Then, they also had baseline labs and followup labs. And then, they had the D&E done in the usual way, by either an attending or a resident surgeon.

Q. What were the results of the efficacy study? What were the conclusions that you reached after you conducted the study?

A. The conclusions were that the use of intra-amniotic digoxin did not make the procedure safer by any of the ways that we could assess it.

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Q. Could you show us where? Describe for us this table.

A. So, this table is a list of the symptoms or adverse effects that are most commonly associated with digoxin.

And again, if you look at that whole list of symptoms, you know, even though women have them in both groups, if you look at the p value, the only p value that is less than .05, meaning statistically significant, is for vomiting. And in that, about 16 percent of the digoxin group had vomiting, whereas only 3 percent of the placebo group had that symptom.

Q. In your opinion, is that a significant difference between the two groups?

A. Yes, because the p value means that that is essentially 98 percent unlikely to have occurred by just chance alone.

Q. Did your study reach any other conclusions or make any other findings of significance?

A. That the digoxin was not uniformly effective in causing fetal demise within the approximate 24-hour duration.

Q. What was the conclusion about the effectiveness of digoxin causing fetal demise?

A. In 8 percent of the subjects who received digoxin, there was noted to still be a fetal heartbeat at the time of the D&E.

Q. So do you have any overall conclusions about the study, the efficacy study?

[325]

A. Our overall conclusion was that digoxin did not make the D&E—the intra-amniotic digoxin did not make D&E's easier. It didn't make them safer. And it didn't improve the procedure by any objective measure that we could assess.

The only significant difference between the two groups was that the digoxin group had more vomiting.

Q. So did you—do you have any opinions as to whether digoxin has the potential to cause adverse maternal outcomes?

A. I did. I mean, I think that clearly clinical experience has shown us that digoxin is safe overall. But, we know just sort of by medical common sense that if you use a medicine or an intervention often enough, there can be adverse events associated with that medication.

So, I mean, vomiting is unpleasant, but it is not a particularly severe complication for most patients. But, you know, if you use a medication that potentially has effects on cardiac rhythm or even just the amniocentesis injection process itself, eventually you may have a rare but significant risk associated with that.

Q. What type of rare but significant risks could you have from the injection of digoxin?

A. I mean, most dramatically, but I am sure, very clearly unusually would be to cause an arrhythmia that could even lead to the stoppage of the heart, and you wouldn't expect to see that often, and apparently we haven't. Because we would expect [326] people would report that, and that case would make it into the medical literature, and it never has.

So that is good. But, then other problems could be just more commonly the problems like infection that is caused by taking what has been a sterile space, usually sterile space around the fetus and now broaching that and entering—you know, putting something in there that is potentially going to cause an infection.

So that is a risk leading—causing miscarriage before your abortion procedure. Those are some of the risks.

Q. Are there risks associated with the infection that could be caused by, as you said, broaching the otherwise sterile space?

A. I think from obstetrics we are unfortunately all too aware of how serious—I am sorry—infections can be within the uterus. Because essentially we view that space as—we call it "a growth medium," essentially. It is a very rich area for bacteria. Potentially could cause a very serious infection.

So we worry a lot when a woman has an infection in her uterus that it can sort of really develop quite quickly into a serious infection and cause sepsis and potentially even death.

So usually if a woman has a significant infection in her uterus you want to get that infection out of her uterus because it can be so life-threatening.

Q. And you want to avoid it, as well?

[327]

A. And you want to avoid it. You really don't want to potentially take that risk unless you have a good reason to.

Q. And I don't think we have had before a description of what sepsis is. Do you mind describing that to the court?

A. So sepsis is when you have such overwhelming infection, essentially the body in fighting off that infection sort of shuts down. And you end up with low blood pressure and potentially dying from that.

Q. Are there any risks—are the risks with the injection of digoxin any different than the risks that you experience when you do amniocentesis?

A. Our studies don't really look at that specifically, but from just clinical knowledge, the difference ultimately is that in an amniocentesis you are withdrawing fluid. You are just—so that the direction is out. Whereas, in this case you are actually instilling something that has been from the outside in. And though you try to keep the conditions sterile, one would think that you might have more risk of introducing infection going from the outside into the uterus.

Q. And have you seen any situations where the risks were increased as a result of the use of digoxin to cause fetal demise?

A. Well, we had those two cases where we did note that we did something that caused the women to have high digoxin—serum digoxin levels. So that I have seen personally.

[328]

And then, there are cases where women have had serious infections, even lethal infections from amniocentesis. So that is rare.

And I was asked to review a case where a woman received intracardiac potassium chloride to get—to cause fetal demise and where the woman suffered a cardiac arrest where her heart stopped.

Q. Do you know what happened in that case?

A. Oh, she was resuscitated. She had measures to resuscitate her, and she lived.

Q. And then, in addition to the adverse maternal outcomes, you previously talked about vomiting as a side effect?

A. Right.

Q. Is that the most significant side effect that you are aware of?

A. That we saw in our study.

Q. Are you aware of any other side effects from your clinical experience?

A. Just the discomfort of the injection. I haven't seen—personally, I haven't seen other side effects from it.

Q. So after you completed the two safety—

A. I am sorry, except the women miscarrying all over the Bay Area. That was another side effect. Sorry.

Q. So after you completed the safety and efficacy studies, did the practices at the Women Options Center change in terms of [329] their use of digoxin?

A. Yeah, we—I would say that our providers almost immediately very much decreased their use of digoxin because we had been using it in order to make these procedures safer.

But when, by the best study we know how to do, we didn't show that it made the procedures safer, we pretty much abandoned using it before D&E.

Q. And why was it abandoned?

A. Because you don't want to first cause pain in the woman. Second, put her at risk for something that you don't actually think is in her benefit as a patient.

Q. Do you personally offer digoxin now to your patients?

A. Yes.

Q. Do you do it routinely?

A. No, I don't offer it routinely. I will offer it if the woman specifically asks for it, I will go through my understanding of the risks, benefits and alternatives as I would normally consent someone.

And we also do offer it before induction terminations of 22 weeks and above.

Q. Does the Women's Options Center have any protocols for the use of digoxin?

A. We do.

Q. Why do you have those protocols?

A. They provide our doctors with guidelines that they can use [330] to provide intra-amniotic digoxin safely, should they choose to use it.

MS. PARKER: Your Honor, may I approach the witness?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Drey, I would like to show you what has previously been marked as Exhibit 35. Have you seen that before?

A. Yes.

Q. And what is it?

A. That is our protocol for the use of intra-amniotic digoxin before D&E.

MS. PARKER: And if I may, your honor, I would like to put it on the ELMO.

THE COURT: All right.

THE WITNESS: I have to say I never noticed this before. Obviously, it is really just the protocol about the intra-amniotic use of digoxin, in general. But it applies to D&E, as well as induction, because that both are mentioned. I have never noticed that before.

BY MS. PARKER:

Q. Does the protocol include the risks of administering digoxin?

A. Yes, it does.

Q. And are those risks essentially the ones that you have been speaking about this morning?

[331]

A. Yes. And the risks are ones that are associated with therapeutic use of digoxin. But we also added the risk of lack of effectiveness. We could include that because of our—the data we had received from our clinical trial.

And then, again, we also included the information about vomiting from our clinical trial.

Q. So could you just read those seven risks for the record?

A. The risks are complications of amniocentesis. And these include: amnionitis, which is infection; amniotic fluid leakage; vaginal bleeding; the onset of spontaneous labor, which I have been discussing as miscarriage; lack of effectiveness. Digoxin was not noted to cause fetal death within 24 hours one out of 10 times; GI symptoms, most frequently nausea and

vomiting in approximately 15 percent; diarrhea or abdominal pain; cardiac arrhythmias, including ventricular premature contractions, ventricular tachycardia; atrioventricular dissociation; sinus bradycardia; AV block and complete heart block; CNS—that is central nervous system—abnormalities; visual disturbances, headache, weakness, apathy and psychosis; and, finally dermatologic reactions, such as maculopapular rash.

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Q. Have you had any recent situations where you have encountered this where the situation was deteriorating so rapidly that you didn't have enough time to administer digoxin?

A. Yes. There was a patient who I took care of who was unsure about whether she wanted to continue her pregnancy, but then started having very high blood pressures. And because she was concerned about her other two children and the risks to her health that this pregnancy appeared to be causing, she decided to terminate.

And, in fact, by the time she made that decision her blood pressures were so high that she had to be admitted to the hospital while waiting for her abortion. So we intended to do the abortion the following day. She was diagnosed with a condition called "severe preeclampsia." And it was even worse than the usual severe preeclampsia, because it was affecting her liver and causing her liver to fail.

And it was also causing her to lose her ability to clot. And so we placed laminaria intending to do the abortion

the following day, but actually because her platelets, her clotting factors continued to drop overnight, I was actually [334] called into the hospital in the middle of the night, and we did her D&E at about 2:30 in the morning.

Q. Did you administer digoxin in that case?

A. No.

Q. Do you recall what gestational age she was?

A. I believe she was 22 weeks.

Q. I believe when Ms. Morris was asking you some questions she talked to you about the impact of the Partial-Birth Abortion Ban Act on the Women's Options Center at San Francisco General; is that right?

A. Yes.

Q. And you indicated that you were concerned about the impact on the Center; is that right?

A. Yes.

Q. And what would that impact be, just briefly?

A. I would be concerned that we would no longer be able to provide these services, second-trimester abortions. I mean, by D&E.

Q. Would you consider using digoxin to avoid violating the Act?

A. That would be really a very painful decision for me to make, and I would really have trouble doing that.

Q. Why is that?

A. Because when you usually do a medical intervention on a patient it is for her benefit. So, if I am going to use [335] digoxin, for example, it's—and when I consent her for digoxin, I am saying that I think this

is for her benefit and that the risks are small and that whatever benefit is involved is worth those risks.

I wouldn't even have any idea how to consent a patient if I am giving digoxin for my benefit as a provider. So I don't know what I would say. I wouldn't be saying that this is for her clinical benefit. I would be saying:

> "Well, I need to give you digoxin because otherwise I can't perform your abortion."

So, it is not for her clinical benefit. It is for me. And I just—I would feel very much forced to do something to a patient that wasn't for her. That would just really be awful for me.

Q. And are there situations where even if you used digoxin you would still violate the Act?

A. Well, from our study, if we used digoxin as we felt was safest, which—and the way we felt we could do most reliably, which was intra-amniotic digoxin, I wouldn't have achieved fetal demise within 24 hours 8 percent of the time.

So in that case, even if I gave digoxin to protect myself, in fact, I could still be violating the act in trying to then finish the D&E.

And then, there are situations where, again, if I have used digoxin, but then I felt for clinical reasons I had [336] to proceed with the abortion before I had planned, I would be violating the Act.

And then, there are situations that are emergent where a woman's health may be at risk, but I don't have time to give digoxin, where again I could be violating the Act. And I don't know what I would do in those situations.

Q. Would there also be situations—well, I guess if it was contraindicated you wouldn't be using it.

A. Right. Yes, I mean, in women in who it is contraindicated.

Then, there are the women who I can't get there from here. I mean, it's funny. Looking at this needle, in some ways it looks long. If you are the woman who is having the injection, it looks quite long.

But if you are the doctor doing the injection, sometimes it just doesn't look long enough, because you can't—you know, you can put it up to the hub and still not be able to get where you want to go. So if I can't physically get there, I might not be able to administer digoxin that way.

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[340]

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Q. Now, doctor, causing fetal demise before D&E makes the fetal tissue easier to disarticulate?

A. Yes.

[341]

Q. In your efficacy study, the second study that you testified to in your direct examination, the physicians who performed the D&E's after the injections, whether with digoxin or placebo, those physicians were able to guess whether the patient received the digoxin or a placebo 75 percent of the time?

A. Yes, but you would have expected them to get it right 50 percent of the time. So 75 percent of the time wasn't really as high as we expected.

Those of us who had been using digoxin thought we would always know. And, in fact, we weren't as right as we thought we would be.

Q. And the reason you thought the doctors would always know is that it makes it easier to disarticulate the fetus?

A. The tissue is softer, so it is easier to disarticulate, but that can also make it easier to actually—I am sorry—more difficult to actually complete the abortion.

Q. How is that?

A. Because if the tissue is very soft, instead of being able to draw the fetus down into the lower part of the uterus where it is safer to do the abortion, it may stay up higher in the uterus, and you may have to have more passes with the forceps to draw the fetus out.

So, the downside of having softer tissue is that if it comes apart very easily you have to make more passes, and you have to go up higher in the uterus.

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[DREY—CROSS EXAMINATION]

[350] digoxin injection?

A. It is an initial attempt to say that the medication is safe enough that you feel that you can proceed to administer it to a large number of patients. It doesn't mean that even if you do a safety study that the medicine is necessarily universally safe.

Q. Now, your efficacy study, doctor, which you have in Exhibit 30, that involved injection of digoxin into 126 subjects, correct?

A. Yes.

Q. And no complications occurred in any of those patients?

A. There were complications. There were no complications that we specifically associated with the digoxin injection. I mean, there was one major complication.

Q. But, again, it was not associated with the injection?

A. We—you know, there's the science end of it. We can't specifically say it was associated with the digoxin injection. At the same time, I was explaining that my concern with digoxin is that, you know, potentially the tissue is softer so you have to reach up higher in the uterus.

And as you heard earlier when you have to reach up higher in the uterus you are concerned that you might perforate the uterus.

And the one patient who had a uterine perforation had received digoxin. Now, you can't conclude that it was the * * *.

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

TRANSCRIPT OF PROCEEDINGS
Thursday, Apr. 1, 2004
Volume 3

BEFORE THE HONORABLE
PHYLLIS J. HAMILTON, JUDGE

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THE COURT: It's fine. He is testifying under the pseudonym. We will refer to you as Dr. Doe.

THE WITNESS: Thank you.

[DR. DOE—DIRECT EXAMINATION]

BY MS. PARKER:

Q. Good morning, doctor. I am Beth Parker, one of the attorneys for Planned Parenthood.

Have you come to Court today prepared to state your opinion about the Partial-birth Abortion Ban Act and the impact [378] it will have on your practice?

A. Yes.

Q Before we get into that opinion, I would like to ask you some questions about your practice.

You're an OB/GYN; is that correct?

A. Correct.

Q. And do you have a specialty?

A. I have a subspecialty in perinatology or maternal-fetal medicine. They are the same field.

Q. Are you board certified in any field?

A. I am board certified in obstetrics and gynecology and I'm board eligible in maternal-fetal medicine.

Q. What does that mean to be board eligible?

A. I have completed my fellowship. I have passed my written exam for the board, and I am currently collecting cases for—to sit for the oral exam.

Q. And in California do you need to practice a period of time before you can get your certification for OB/GYN, and then for perinatology?

A. Well, not only in California, but throughout the United States. To be board certified you have to practice for a period of time, collect those cases, and then, the exam, oral exam, is based partially on those cases.

I had to do that for general Obstetrics/Gynecology and then, again, for maternal-fetal medicine.

[379]

Q. Where do you currently practice?

A. California Pacific Medical Center.

Q. What position do you hold there?

A. I'm a staff physician and a member of the Maternal-Fetal Medicine Associates.

Q. You recently joined California Pacific Medical Center; is that right?

A. Correct, in October.

Q. Where were you before that?

A. I was at the University of California at San Francisco.

Q. What department were you in at UCSF?

A. Department of Obstetrics, Gynecology and Reproductive Sciences in the Division of Perinatal Medicine.

Q. Did you do a fellowship there?

A. Yes, I did my Maternal-Fetal Medicine Fellowship at UCSF.

Q. Did you also work at the Fetal Treatment Center at UCSF?

MR. QUINLIVAN: Your Honor, I know these are just background questions, but these are leading questions.

THE COURT: But because they are background, I generally permit leading for background.

MR. QUINLIVAN: Very well. Thank you.

THE COURT: And you may do so, as well.

MR. QUINLIVAN: Okay. Very well. Thank you, Your Honor.

THE WITNESS: The Fetal Treatment Center was an [380] entity that was in the conjunction with the Department of Surgery and the Department of Obstetrics and Gynecology.

BY MS. PARKER:

Q. And what does it do? What does it do?

A. The goal of the Fetal Treatment Center is really to provide accurate prenatal diagnosis and the termination, if certain fetal abnormalities might be amenable to procedures in utero that could correct, say, a defect and continue the pregnancy on, and then hope that that would be a better outcome than just repairing the defect after birth.

Q. And what role did you play at the Fetal Treatment Center?

A. I was the primarily the obstetrician who counseled the patients ahead of the procedures, helped to make the diagnosis.

If the patients had therapy were present at the therapies, and then took care of their pregnancies after the therapies.

Q. And did you do that as part of the team?

A. Yes, it was a very big team. It included perinatologists, pediatric aurgeons, neonatologists.

Q. And what is a neonatologist?

A. A Nesonatologist is a pediatrician who has done a fellowship in Neonatology. And that is the care of the premature babies, basically.

There is also anesthesiologists, radiologists and a social worker as part of the team.

Q. How long did you work at the Fetal Treatment Center?

[381]

A. I started doing some work during my fellowship at UCSF, and then I was on staff at UCSF for five years after that. The whole duration I was involved with the Fetal Treatment Center.

Q. Did you also teach at UCSF?

A. Yes.

Q. What did you teach?

A. I taught Clinical Obstetrics and Gynecology to medical students and residents.

Q. Do you currently focus on both on issues of maternal conditions and fetal abnormalities?

A. Yes.

Q. What types of patients do you see currently in your practice?

A. It's a mixture of women who have medical problems going into a pregnant that may impact the pregnancy, as well as conditions that develop during a pregnancy that make it more complicated, or the diagnosis of fetal abnormalities.

Q. And what type of patient care do you provide?

A. I—a few patients of ongoing care during their entire pregnancy. The majority of pregnant—of women as co-managing their consults, and then providing prenatal diagnostic services, which include ultrasound and amniocentesis.

Q. What is amniocentesis?

A. It is a procedure used to try to diagnose a chromosome abnormality in utero. We take a very small needle under [382] ultrasound guidance, place it through the internal abdominal wall into the uterine cavity where the amniotic fluid is; withdraw some amniotic fluid and then remove the needle.

The amniotic fluid then can be tested for a variety of things, particularly in these situations the chromosomes of the fetus.

Q. Do all OB/GYN's regularly perform amniocenteses?

A. All OB/GYN's are trained initially in their residency to do an amniocentesis. The vast majority of general OB/GYN's do not perform amniocenteses regularly in their practice.

In the State of California, the AFP program has kind of de facto made it that only perinatologists perform genetic amniocenteses. The AFP program is a program used to try to detect certain birth defects and karyotype abnormalities.

It is performed from a serum or blood test on the patient. If the results are abnormal she is then referred to a center called a Prenatal Diagnostic Center. Those centers are very closely-regulated in regards to their ultrasound abilities and the outcomes or complications that they have with amniocenteses.

And by this mechanism it is kind of de facto made that only the perinatologists wind up doing genetic amniocentesis in California.

Q. And how many of those prenatal diagnostic centers are there in San Francisco, for example?

[383]

A. I think there are four in San Francisco.

Q. Do you also do what is known as CVS? First, why don't you tell the court what CVS is?

A. CVS or chorionic villus sampling is another type of procedure to diagnose karyotype or chromosome abnormalities.

It is basically a biopsy of the placenta. It is done at an earlier gestational age, and I was not trained to do this procedure in my fellowship, so I do not do it.

Q. Do you perform abortions in the second-trimester?

A. Yes.

Q. Under what circumstances?

A. The circumstances that I provide the abortions are in conditions of maternal disease that could certainly worsen during the course of a pregnancy. Conditions that develop during a pregnancy that puts the maternal health potentially to worsen or in fetal condition—fetal abnormalities.

Q. Okay. So you described three circumstances where you might perform an abortion in the second-trimester. I would like to talk briefly about each of those, if I might.

Could you give us some examples where continuing the pregnancy would compromise the mother's health?

A. There are a lot of medical conditions that can on do it specifically one is something called Eisenmenger's syndrome.

This is a medical condition that is due to usually a congenital heart abnormality that allows communi-

cation of blood from the [384] right side of the heart to the left side of the heart.

The normal situation is that the blood pressure in the pulmonary vasculature is much lower than the blood pressure in the systemic vasculature. You get a little bit of a shunt of blood to the lungs.

That is not a big problem. However, it eventually causes the pulmonary vascular pressure to increase quite a bit.

When you add pregnancy to the mix in these patients that have this disease their systemic pressure drops dramatically during pregnancy. It's a normal phenomena of pregnancy. And you can get a reversal of the shunt of blood, so the blood will then go from the right to the left without going through the lungs.

The patients become—have less and less oxygen in their blood, and this becomes very dangerous. In the object distributing literature, the mortality of this disease in pregnancy is 50 percent. However, it's poorly done retrospective kind of case series.

In the experience of approximately—probably the last eight patients that we took care of at UCSF with this condition all of the women died postpartum.

THE COURT: What was the condition again?

THE WITNESS: Eisenmenger's syndrome.

BY MS. PARKER:

Q. And what is "postpartum"?

A. After delivery.

[385]

Q. Could you give us some examples of some of the fetal abnormalities that you see complicate pregnancy or might suggest an abortion in the second-trimester?

A. The most common I see are karyotype or chromosome abnormalities. Those could be Trisomy 21, which is Down's Syndrome. Trisomy 21. Trisomy 18 or Trisomy 13. These are the most common chromosome abnormalities that I see.

There are other structural fetal abnormalities, such as congenital heart disease, diaphragmatic hernia or spina bifida.

Q. And how late do you perform abortions?

A. I perform abortions to an equivalent of 23.1 weeks gestational age.

Q. How do you measure that?

A. I measure that by the biparietal diameter, which is an ultrasound measurement of the fetal head. And my cutoff is 56 millimeters.

Q. Why do you not go beyond 23.1 weeks gestational age?

A. In my training when I learned the procedures I wasn't trained to go beyond this size of a fetal head.

Q. What methods of abortion do you use in this second-trimester?

A. I use dilation and evacuation and induction of labor.

Q. And what is the breakdown of those two types, approximately?

[386]

A. Approximately 75 percent D&E and 25 percent induction.

MS. PARKER: Your Honor, may I approach the witness?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Doe, I have shown you what has been marked as Exhibit 32. Do you see that?

A. Yes.

Q. Is that your curriculum vitae?

A. Yes.

Q. Is the information in it current?

A. Yes.

Q. Is it true and correct?

A. Yes.

MS. PARKER: Your Honor, I would like to offer 32 into evidence.

THE COURT: All right. Any objection?

MR. QUINLIVAN: No objection, your Honor. I—well—

THE COURT: The copy I have has not been redacted.

MS. PARKER: Has not been redacted?

THE COURT: No.

MR. QUINLIVAN: That was my concern. I did not know: Was this a redacted version or not?

MS. PARKER: Yes. We will substitute with a redacted version. I apologize. I thought we had.

[387]

THE COURT: Actually, I am not even sure the redacted version gives enough information that it is even—you will need to admit it into evidence. You all have stipulated to his basic qualifications. I don't see that you need to have—

MS. PARKER: The C.V. into evidence?

THE COURT: —The C.V. into evidence.

MS. PARKER: Then, we won't do that.

Then, we will move to qualify Dr. Doe as an expert witness in the areas of obstetrics and gynecology, perinatology and abortion practice and procedure.

THE COURT: Any objection?

MR. QUINLIVAN: No objection, your Honor.

THE COURT: It will be accepted.

BY MS. PARKER:

Q. Dr. Doe, have you ever testified as an expert before in a case involving abortion?

A. No.

Q. Are you being compensated for providing expert testimony in this case?

A. No.

Q. Do you have any affiliation with Planned Parenthood?

A. No.

Q. So I want to go back and talk a little bit about some of the conditions that you treat. Do your patients ever choose to [388] end their pregnancy due to a maternal health condition?

A. Yes, they do.

Q. And does this sometimes arise when medical conditions—with medical conditions that a woman had before becoming pregnant?

A. Yes.

Q. I know you gave us an example of Eisenmenger's syndrome. Are there other examples you could provide?

A. Other examples would be primary pulmonary hypertension, again, can lead to some of the same problems where the pulmonary vasculature has very high blood pressure leading to low oxygen in the blood and high risk of mortality.

Another condition would be type I diabetes with multiple vascular complications. And what I mean by that is that their kidneys are affected and don't have normal kidney function, or they have kidney—they won't have normal kidney function, or impaired vision, because the diabetes has affected the blood vessels that supply blood to the eyes.

Q. And are there any others that you can think of, conditions that a woman has before she becomes pregnant?

A. None right now.

Q. Okay. And would the patient know she has these diseases before she became pregnant?

A. The patient may know this or may not know that she has these diseases, depending on her access to care and how often [389] she's seen a physician and whether the physician has necessarily picked up on these problems or not.

Q. If she chose to terminate the pregnancy, when in the pregnancy would she make that decision, typically?

A. Well, I mean, ideally it would be as soon as possible, because the ongoing process could continue to effect the disease. But often these decisions aren't—or diseases and referrals aren't made until the second-trimester.

Q. Are patients sometimes forced to—or are patients sometimes choose to end a pregnancy due to a medical condition that is created by the pregnancy?

A. Yes.

Q. And could you give us some examples of those?

A. It would be rare, however. Severe preeclampsia is something that could present in the second-trimester. Then cervical incompetence, the premature rupture of membranes, to other conditions.

Q. What is preeclampsia?

A. Preeclampsia is a disease of pregnancy that is probably due to a placental abnormality. It manifests itself by hypertension in the patient, as well as protein in the urine, and can then effect all organ systems within the body.

Q. And is it fairly serious, preeclampsia?

A. Yes, it is very serious. And pretty much prenatal care was developed to diagnose preeclampsia. The whole reason that—[390] if you know at many prenatal

visits you have your blood pressure taken and you give a urine sample it is all to be able to pick up preeclampsia.

Q. What happens if preeclampsia is not diagnosed?

A. If preeclampsia is not diagnosed it could lead to kidney failure, rupture of the liver, a seizure and ultimately death.

Q. And you indicated that preeclampsia sometimes arises in the second-trimester?

A. Correct.

Q. And when that occurs what choices does the pregnant woman face?

A. It really depends at what point in the second-trimester, but if it is certainly before viability, it is unlikely and unsafe to try to continue the pregnancy to viability, and really the only choice is termination of the pregnancy.

Q. You indicated another example was cervical incompetence of a condition that is created by the pregnancy itself. What is cervical incompetence?

A. The cervical incompetence is that the cervix is unable to kind of hold and maintain the pregnancy, per se. The cervix is structurally weaker, for some reason, and will just kind of, without pain or contractions, dilate and open up. And usually these can lead to extremely premature delivery, or could lead to a subsequent other problem was premature rupture of the membranes.

[391]

Q. And what happens if cervical incompetence occurs in the second-trimester? What choices does the pregnant woman face?

A. The choices involve kind of what we call expectant management, kind of putting the person to bed and hoping that the pregnancy doesn't kind of proceed to go on to deliver. But it is high risk of delivering a fetus that's extremely premature.

Another option is something called a "rescue cerclage" in which we try to put a stitch into the cervix and close it up.

In the situation where the cervix is already dilated from cervical incompetence and doing this after the fact rather than as a prophylactic measure, the results are pretty dismal with the rescue cerclage.

And then, the final choice would be a termination of pregnancy.

Q. Are their risk factors for women who have cervical incompetence?

A. Yes. They include women whose mothers took DES. It is a medication that was a hope to try to decrease the chance of miscarriage. However, in the female offspring of women who took this medication, they are at higher risk for a number of gynecologic complications: cervical incompetence is one of those.

Other known risk factors are greater than three [392] second-trimester terminations and certain collagen vascular diseases could put the patient at risk for cervical incompetence.

Q. And are there women who have no risk factors who develop cervical incompetence?

A. Yes.

Q. Is that a majority of the cases or not?

MR. QUINLIVAN: Objection, leading.

THE COURT: Overruled.

THE WITNESS: I would say most patients you can identify some risk factor, but there is a considerable number of patients that have no risk factors whatsoever.

BY MS. PARKER:

Q. And I think the third example you gave us of a health condition that can develop during pregnancy that might cause a woman to choose to terminate the pregnancy was premature rupture of the membranes; is that right?

A. Yes.

Q. And could you describe for us what that is?

A. That happens when the amniotic membranes have a hole rupture in them, and the amniotic fluid leaks out. This puts the patient at considerable risk for infection and potentially very severe infection. Results in trying to maintain the pregnancy at this point are kind of uniformly dismal. The usual recommendation is for both maternal health and for the [393] poor potential outcomes for the fetus is to terminate the pregnancy.

Q. What is the general time frame that these three conditions that you've talked about manifest themselves?

A. All in the second-trimester.

Q. And if a pregnancy termination were indicated for their conditions, when would that pregnancy-termination occur?

A. In the second-trimester.

Q. Do your patients ever choose to end their pregnancy due to a fetal anomaly?

A. Yes.

Q. Can you give us some examples of those?

A. I would say the first example is a category of chromosome abnormalities, and these include trisomy 21, also known as Down's syndrome; Trisomy 18; Trisomy 13. However, there are a number of other fetal chromosome abnormalities that are less common that are sometimes diagnosed.

Q. Are any of these lethal?

A. Yes, Trisomy 18 and Trisomy 13 are considered lethal.

Q. What is Trisomy 18? How does that show itself?

A. Trisomy 18 is a condition where there is three copies of chromosome number 18. It is usually—well, not always, but often can be diagnosed prenatally by kind of a multitude of fetal abnormalities that are—that can be seen, structural abnormalities that can be seen on ultrasound, often prompting [394] amniocentesis.

Additionally, the AFP test helps screen for Trisomy 18, so you can identify some women who might be at higher risk for this, and then warrant the amniocentesis.

Q. And how does—what about Trisomy 13?

A. Trisomy 13, there's not a blood test that helps screen for it, but usually the fetus has structural abnormalities that are consistent with the condition.

Q. You indicated there were additional fetal abnormalities in addition to the chromosomal ones you just mentioned?

A. Yes. Those can be identified, I guess, as structural abnormalities. Those include congenital heart disease. Now, some aspects of congenital heart disease are very mild and can be very normal, while others are very severe and may die or have a very, very difficult life with multiple hospitalizations and sick their entire life.

A condition called "congenital diaphragmatic hernia" is a situation where the diaphragm doesn't form appropriately, and liver and intestines can be up into the chest. This does not allow the lungs to develop appropriately, and it is very high, high likelihood of death at delivery. Or if the infants do survive, they have multiple, multiple medical problems and require multiple surgeries, long stays in hospitalization, and baseline intelligence is significantly decreased.

Q. In addition to congenital heart disease and congenital [395] diaphragmatic hernia, are there any other structural abnormalities?

A. One of the other or two most common ones are neural tube defects, which could be—anencephaly is on one spectrum is where a brain doesn't appropriately develop. And there is development of the cranium up to the level of the eyes, with nothing beyond that.

There is a brain stem, but no more brain tissue and they have no higher functioning whatsoever. As well as another type of neural tube defect is something called "spina bifida" where there is an opening or splaying of the spine that allows the exposure of the spinal cord. And often the patients are paralyzed from that level downwards.

Q. Are any of these structural anomalies lethal or potentially fatal to the fetus?

A. Some of them can be lethal, yes, and many of them are associated with decreased life expectancy for the infant, as well as major difficulties kind of growing up and hospitalizations, multiple infections, other such things.

Q. So in addition to the Trisomies, and then the structural anomalies, are there any other type of fetal anomalies?

A. There are other fetal abnormalities that I guess we can coin kind of as genetic, that there is a particular single gene that is missing.

Examples of these are something called Tay-Sachs [396] Disease or Canavan's Disease.

Another example is something called Spinal Muscular Atrophy. Many of these are degenerative, neurologic conditions. The fetus is born alive, however eventually the infants stops making its milestones, and then kind of deteriorates and ultimately dies.

Q. And you indicated these were genetic diseases. Are they seen in certain population groups?

A. They are often in some population groups that have higher risks of autosomal recessive diseases. And this is where both parents are carriers for a particular gene and you have to be missing both copies of the gene for the disease to manifest.

A population such as the Ashkenazi Jews are one that is at particularly higher risk for Tay-Sachs and Canavan's Disease.

French Canadians are at higher risk for Tay-Sachs, as well. There are genes that effect hemoglobin, which is the blood-carrying molecules. And in populations, Mediterranean and African populations, as well as

Asian populations, they are at higher risk to have Thalassemia.

Q. In what general time frame of pregnancy are abortions for fetal conditions typically performed?

A. They are typically performed in the second-trimester.

Q. Why is that?

A. Because diagnosis isn't made until the second-trimester.

[397]

Q. How is diagnosis done for these various fetal abnormalities?

A. The chromosome abnormalities are done by amniocentesis or chorionic villus sampling.

The structural abnormalities are diagnosed by ultrasound. And that ultrasound really needs to be performed in the second-trimester because it is just too difficult to see some of these structures at an earlier gestational age.

Q. So when you are doing the ultrasound diagnosis for the structural abnormality, approximately when does that ultrasound happen?

A. Usually between 18 and 20 weeks gestation.

Q. And when you use ultrasound, can you do a complete diagnosis of the structural abnormality?

A. Sometimes you can. Sometimes you can't.

Q. If you can't, do you need to do any additional diagnosis?

A. Sometimes amniocentesis is done. There are conditions sometimes that we know that this is a very

severe condition, but we don't have the exact diagnosis. Without having the exact diagnosis we can't give a recurrence risk. And we might recommend a fetal autopsy be done.

Q. Let's talk for a moment about the amniocentesis. You indicated that was another diagnostic tool that you use to determine a chromosomal anomaly; is that right?

A. Yes.

[398]

Q. And when is amniocentesis typically done?

A. Typically done between 15 and 20 weeks gestation.

Q. And how long does it take to get the results?

A. Approximately seven to 14 days.

Q. And does amniocentesis present any special risks to the pregnant woman?

A. Yeah. The risks of amniocentesis as kind of with any procedure are bleeding and infection, and in this situation, also, kind of loss of the pregnancy.

Q. Do you typically do amniocentesis on every pregnant woman?

A. No . You could argue maybe be offered for every pregnant woman, but it is typically offered to women that appear to be at higher risk for these problems. It's been in the United States kind of age 35 and beyond.

But if we also diagnose an abnormality in ultrasound or their blood AFP test is abnormal, the patient is referred to genetic counseling and talking about the risks of having one of these abnormalities and

the risks of the procedures. And then, they decide whether they want to proceed with the procedure.

Q. Are there any fetal anomalies of the ones you have talked about or others that will actually increase the risks of pregnancy?

A. There is one particular chromosome abnormality that could increase the risk of preeclampsia at a very early gestational age, and this is called Triploidy.

[399]

Q. And what happens with Triploidy? Why don't you first tell us what Triploidy is?

A. Triploidy is that you have a karyotype of 69xxy. So you have an extra kind of path to the karyotype, so it is way too many. You have placenta and fetal abnormalities, and you have very large placenta. And it appears to be, for some reason we don't understand, a much higher risk of development of preeclampsia, and usually development of preeclampsia in the second-trimester.

Q. And what—when that happens, what is the general recommended course?

A. Termination of pregnancy.

Q. And why is that?

A. Because the fetus isn't normal, for one. And for number two, that the preeclampsia will proceed and the potential complications of the preeclampsia are very severe, as I had mentioned earlier.

Q. Now, you indicated that you currently use two methods of abortion in the second-trimester; is that right?

A. Yes.

Q. I think the first one you mentioned was a D&E?

A. Correct.

Q. Dilation and evacuation. What is your goal in performing a D&E abortion?

A. My goal is to do the procedure as safely as I can for the [400] woman.

Q. And how do you achieve that?

A. I achieve that by trying to make as few passes into the uterus.

Q. Why is that?

A. Because we know that the major risks of the procedure are associated—are infection, bleeding, uterine perforation.

And by making a pass with these instruments into the uterus that is when you are at risk for having these complications.

The more times you have to go into the uterus, the higher chance there is of a complication.

Q. What do you base that opinion on, that you want to do it as few passes as possible?

A. Common sense, experience, and I guess extrapolation from other studies that we know of, a certain procedure causes the potential risk of something. The more you do that, the higher the chance of that complication.

Q. Can you describe for us how you perform a D&E procedure?

And actually, before you do that, would it be helpful if you used a picture of a—

A. Yes.

Q. —of the anatomy?

A. Yes, I think so.

MS. PARKER: May I approach the witness, Your Honor?

THE COURT: Yes.

[401]

THE WITNESS: First of all, we will counsel the patient regarding her options and what she wants to do with the procedure. We talk about the risk and benefits, and I also talk about the risk and benefits of induction of labor, depending on what the exact indication for the pregnancy termination is.

Usually a day prior to the procedure, then, if she wishes to proceed, we do a placement of laminaria. And we put a speculum within the vagina which opens up and allows us to visualize the cervix, which is right here (indicating).

We place the laminaria, which are kind of osmotic dilators, into the cervix after washing it off with an iodine soap and putting some local anesthesia into the cervix.

The following day the patient would come, in my situation, to the hospital. She would meet the pre-operative nurse. She would meet the anesthesiologist. She would have an IV started. She would have some blood work drawn.

I would meet again with the patient to make sure she didn't have any questions prior to the procedure. And then, she would be taken to the operating room.

BY MS. PARKER:

Q. Before we go there, I have couple of questions about the laminaria. How many, typically, do you use, laminaria?

A. It depends on the gestational age of the fetus and on whether or not the patient's had a vaginal delivery before.

[402]

Q. And what is the factors with gestation age? Is it more or less?

A. The bigger the gestational age, the older the fetus is, the bigger the fetus is going to be, the more dilatation I am going to need. That means the more Laminaria I am going to put in.

Q. Do you ever use a second set of laminaria?

A. Sometimes I use a second set of laminaria, depending again on gestational age and how many I am able to place the first time.

Q. Can you predict the amount of dilation you are going to get from the laminaria?

A. You can have a very rough prediction, but most of the time I can't predict that well how much dilatation I am going to have.

I think I have—I am going to know enough to complete the procedure. Whether it is very dilated or just enough to do the procedure, I think is very, very hard for me to be able to predict.

Q. So you indicated the woman comes back 24 hours later. Does she stay in the hospital for the first 24-hour period?

A. No, she doesn't. She has the laminaria placed, and then she is able to go home.

Q. So you indicated she comes back on the second day, and then what happens?

A. She comes back the second day. Again, she's met the nurse, [403] the anesthesiologist, asked any other questions that she has.

She is then—we make sure she is the correct patient. She is then taken to the operating room, and she's given a general anesthetic.

Next, the patient is placed in stirrups, and then a —her perineum, part on the outside of the vagina and legs are prepped with a betadine solution.

Next, the speculum is placed again within the vagina. I remove the laminaria that have been there previously and make sure the dilatation is adequate for the procedure.

I again prep both the vagina and cervix with this iodine soap.

Next, I administer a medication called vasopressin, which is a vasoconstricting agent that will help decrease blood loss, and I give this injection into the cervix.

I use ultrasound when I do the procedure, so I have continuous ultrasound watching while I do the procedure because I think it decreases the risk of uterine perforation. And that is how I was trained.

Next, a suction cannula is placed within the cervix up into the fundus of the uterus, and then there is kind of a turn of the wrist and the amniotic fluid is then aspirated.

Q. What do you mean by "aspirated"?

A. The cannula is attached to a suction machine. It is kind of—the amniotic fluid is then sucked out.

[404]

Next, I proceed with using a forceps instrument called a Bierer forceps, usually, to extract the fetal tissue.

Upon completion of the procedure, that I make sure that all fetal parts are present, and I make sure that the placenta is removed.

I watch to see if there is any continued bleeding, either from the cervix or above the cervix from the uterus. Once I am sure that there is no further bleeding, an instrument, which I forgot to mention, that is put on the anterior of the cervix, called a "tenaculum" to kind of help hold it in place, I remove that. And I remove the speculum. The patient is woken up and taken to the recovery room.

Q. Do you ever use misoprostol, and what is misoprostol?

A. Misoprostol is a medication that can be used to induce labor.

Q. Do you ever use it during the D&E procedure?

A. I sometimes use misoprostol in the D&E procedure if I have a very advanced gestational age or a cervix that I couldn't get many laminaria in. I sometimes have the patient come the day of the procedure a little bit earlier, and we give misoprostol prior to kind of soften the cervix and make it dilate a little bit more.

Sometimes, additionally, which I didn't mention, sometimes the cervix isn't quite dilated as much as I need, and we have instruments to help dilate that. And

occasionally I [405] have to do that. And when, in my experience, when I have given misoprostol ahead of time, that dilatation appears to be a little bit easier if I need to do it.

Q. Do some women deliver the fetus partially as a result of the misoprostol?

A. Yes, they can.

Q. And when that happens, could the fetus be outside the uterus past the navel of the fetus?

A. Outside the uterus, yes, and potentially even outside the vagina.

Q. And could it be alive?

A. Yes.

Q. And when that happens, how do you complete the procedure?

A. Usually, if the fetus is coming out, the easiest method is to try to do how we would do a breech. It often comes out in a breech presentation. And, again, that is feet first, head second. We do the similar maneuvers that we would do to do a breech delivery.

However, sometimes the cervix is not dilated enough to allow the calvarium to pass.

Q. And what do you then do?

A. I would separate the calvarium from the body.

Q. When you perform the evacuation in the typical D&E, do you ever need to convert the lie of the fetus or the direction of the fetus?

[406]

A. Sometimes. Sometimes the fetus is, again, what we would call vertex or cephalic. And that is when the head is presenting at the cervix.

The head is the difficult—the most difficult portion to deliver in these procedures, and occasionally I will see if I can deliver the cranium initially. Often that doesn't work, and I would need to reach in a little bit higher up with the forceps, grasp the lower extremity and pull down, and that kind of converts the presentation to a breech presentation.

Q. When you are doing your regular procedure, does it ever happen that you bring out the fetus intact or partially intact up to the head?

A. Yes, sometimes it does.

Q. Approximately how many times does it happen in your procedures?

A. Maybe 15 to 20 percent.

Q. And when this happens, do you consider it to be a different procedure from an abortion than one which is disarticulated before that point?

A. I don't think it is different, and I feel fortunate when it happens in some ways, because I think that I will then have less passes into the uterus, and I think less chance for injury or infection.

Q. Before beginning the D&E procedure, can you predict if that is going to happen or not?

[407]

A. I don't think you can predict. There have been plenty of cases where I think I am going to be able to get out the fetus without disarticulating it, and I

cannot. But there have been cases where I think I am going to have a—it is going to be a difficult one, a hard one, and I am able to deliver the fetus intact.

Q. And is there anything that determines whether it will be able to come out intact or partially intact?

A. I mean, I think ultimate cervical dilatation does, but then, even beyond that sometimes I think it is therefore unpredictable.

Q. In your opinion, is it safer if the fetus emerges intact or partially intact?

A. In my opinion, it is safer if it emerges partially or as intact as possible. I think it is safer.

Q. And why is that?

A. Because then I have to make fewer passes into the uterus with my instruments, and that would decrease chances of infection, chances of uterine perforation or cervical laceration.

Q. In your opinion, are there any special health risks if the fetus emerges intact or partially intact?

A. No.

Q. How long does the evacuation part of the D&E procedure take when you do it?

[408]

A. Usually 15 to 30 minutes.

Q. Do you know when in the course of that procedure the fetus dies?

A. No.

Q. Do you ever pay attention to that?

A. No.

Q. Do you ever use digoxin to cause fetal demise?

A. No.

Q. Why not?

A. In reading the studies, I am not convinced that it has any particular benefit. And it potentially has some risks. And I try not to do things, medical procedures, that have very little benefit and have some risk associated with them.

Q. Now, you also indicated you do induction abortions. That's the other method of abortion you use? Could you—under what circumstances would you do an induction or recommend an induction?

A. I would recommend an induction in situations where the diagnosis of the fetal abnormality—that is often what the indication would be for the procedure—is unclear. And, again, without knowing the diagnosis, it is very hard to give a recurrence risk to these couples.

If we have an intact fetus where an autopsy can be performed we have a better chance of arriving at what the diagnosis is, and then a better chance of having the recurrence [409] risk.

But if we have kind of an unclear diagnosis I usually recommend induction of labor, instead.

Q. Can you describe for us the procedure you use to do an induction abortion?

A. Again, I would thoroughly counsel the patient regarding the risks and benefits of both procedures. If she elected to proceed with induction of labor, she would come into the hospital, have an IV started, and then have misoprostol tablets placed within her vagina,

usually in what is called the posterior fornix, or right behind the cervix, back here (indicating).

Q. Is that typically done in the hospital?

A. Yes.

Q. And then, what happens after the misoprostol is inserted?

A. It takes some time to kind of work to soften the cervix, maybe get it to dilate a little bit and basically induce labor.

Probably in the bulk of the patients it takes 24 hours duration before delivery, but it can be as long as 48 hours.

Approximately 90 some percent of patients will delivery within 48 hours after initiating this process.

Q. And when during in induction does fetal demise occur; do you know?

A. I don't know. It really depends on gestational age, and sometimes the fetus is born alive.

[410]

Q. Are there ever circumstances where an induction has to be converted into a D&E procedure?

A. Yes. I have a particular experience in that if the induction fails, it just doesn't work. If we are going on kind of 48, 72 hours and still no delivery, if there is adequate cervical dilatation it can be converted to a D&E.

Sometimes bleeding could be significant enough that you could convert to a D&E to try to slow the amount of blood loss that is occurring.

Q. And are there any circumstances for which induction is contraindicated?

A. Yes. There are some conditions that induction would be contraindicated. One is placenta previa. That is where the placenta is implanted over the cervix and kind of covering the cervix. The fetus would be up higher. This—the fetus would have to deliver through the placenta, and it causes a tremendous amount of bleeding where the placenta previa is.

So an induction of labor is contraindicated in that situation.

There are uterine conditions where an induction of labor would be contraindicated. That could be previous uterine surgery, something called a hysterotomy, or previous cesarean section. There are different types of cesarean sections.

Q. Why don't we stop there for a moment, because I think you have talked about a couple of conditions we haven't previously [411] mentioned.

What is a hysterotomy?

A. A hysterotomy is an incision through the uterine wall into the uterine to open up the—expose the uterine cavity.

Q. What about a cesarean section; what is that?

A. A cesarean section is a hysterotomy, but it is done to deliver a viable fetus. Now, a cesarean section, there are two types, really, of cesarean sections. It can be what is commonly known and most women wind up having something called a "low transverse cesarean section."

Maybe if I have the other diagram it might help.

MS. PARKER: May I get that, your honor?

THE COURT: Yes.

THE WITNESS: So most women at term would require having a cesarean section. The cesarean incision is made in this kind of lower uterine segment. And when the uterus is pregnant, and the term fetus here is—the uterus is stretched and much, much bigger.

This lower segment stretches out and is very, very thin. It doesn't have a lot of muscle within it that involves kind of contracted portions kind of labor. So if you make a transverse incision down here (indicating), the risk in subsequent pregnancies of that rupturing or opening up is very, very small.

It is approximately half a percent. An uterine [412] rupture can be a catastrophic event for the fetus and for the mother.

At earlier gestational ages, this lower uterine segment may not be developed, and it is not wide enough to do a transverse incision here.

The uterine blood vessels are kind of right here and kind of coming in here and have a tremendous amount of blood going to the uterus in pregnancy.

And if you get out into those you can have quite a bad hemorrhage occur, and potentially a woman can die from that.

We often have to make what we call a classical uterine incision. And this is a vertical incision made up here (indicating) or even up and around what we call "the fundus," or top of the uterus.

This sort of incision is going through a thicker area and a lot of muscle involved in contracting. It has

a bigger blood loss, a little bit harder repair to do. It has a much—in subsequent pregnancies has many greater risk factors than if a woman had a low transverse cesarean section.

Using these misoprostol as such a strong agent to promote very, very strong uterine contractions with an induction, the risk of rupturing that scar is significant.

BY MS. PARKER:

Q. That is why induction is contraindicated where there has [413] been a prior cesarean section or hysterotomy?

A. Correct.

Q. Are there other contraindications for induction in addition to those two?

A. There are, again, some medical indications that theoretically misoprostol would be contraindicated.

It goes back to that pulmonary hypertension or Eisenmenger's syndrome, that the agents that—and misoprostol being the primary one now that causes uterine contractions, also can cause contraction of the muscle within the blood vessels in the pulmonary tree. It can worsen the conditions that we were talking about before.

Q. So that's one example where the medication would make induction contraindicated?

A. Correct.

Q. Are there other examples?

A. Asthma has a relative contraindication. You can get the spasm of the air—the bronchial tree. And

constriction of that is what asthma is. And it could worsen asthma, potentially.

Q. And what about cardiac conditions, ever contraincidated--is induction ever contraindicated for cardiac conditions?

A. Yes. Potentially with the pulmonary hypertension and with the Eisenmenger's syndrome could be. For the same reason, again, of the constriction of the pulmonary vasculature.

[414]

Q. So in addition to the contraindications, are there any just risks of an induction abortion?

A. Certainly there are risks of induction abortion. And the biggest ones are infection, bleeding, and a retained placenta where the placenta doesn't deliver after the fetus delivers. And you subsequently need a surgical procedure, like a D&E, to go in and remove the placental tissue.

Q. And do you have an opinion about the safety of inductions?

A. In my experience, I have had more complications with inductions of labor rather than D&E's. Both have been safe, but I have had more bleeding complications and having an induction kind of fail or placenta not come out, had to take them to the OR. I have basically done both procedures on the patient then.

Q. And could you ever do a hysterotomy if an induction was contraindicated?

A. You could do a hysterotomy if an induction was contraindicated, but hysterotomies have the biggest risk of any of the procedures to end the pregnancy.

And, again, this would be typical to what a classical cesarean section is where you make your incision through the thick portions and muscular portions of the uterus. And not only does it have a much greater blood loss potential and it's an abdominal surgery which has risks of potentially injuring other organs at the time, subsequent pregnancies are greatly at much higher risk [415] than if the patient had a D&E.

Q. And why is that? What are those long term risks?

A. Those long term risks is when you have had a hysterotomy and this big incision coming down here (indicating), the biggest risk is probably uterine rupture in a subsequent pregnancy. And that can be anywhere from about ten to twelve percent risk of a uterine rupture.

Additionally, in women incisions such as that, the uterus really doesn't heal completely normal. And if a placenta implants upon that area, you can get something called a "placenta accreta."

And a placenta accreta is a condition where the placenta grows into the myometrium, or the muscle of the uterus. And it can sometimes become an increta, in which it goes all the way through the muscle. Or sometimes even something called a percreta, which it grows outside of the uterus, and potentially into the fallopian tube, into the ovary, into the bladder, into the vagina, and all sorts of things. Particularly, particularly morbid condition, and the treatment is a hysterectomy at the time of the subsequent delivery.

Q. And what is a hysterectomy?

A. A hysterectomy is where the uterus is removed.

Q. So when you are meeting with your patients and discussing the different abortion methods that they have an option for, do [416] you talk to them about the relative safety of the methods?

A. Yes. I talk to them about the relative safety of the methods, the potential benefits to the methods. And sometimes I won't have much of an opinion of which way they should go. Sometimes I will steer them a little bit. And mainly, in whether or not we need an autopsy or not to give them recurrence information.

Q. And what do you tell them about the risks of the different types?

A. I say that they are close to being essentially equal, however I have had more bleeding complications and needing to go back to the OR to do—to remove a retained placenta with induction.

Q. Now, I think I asked you a few minutes ago—I don't know if you want to sit down. We will move into a different topic.

I asked you whether you ever used digoxin to cause fetal demise when you were doing a second-trimester procedure. You indicated you do not?

A. Correct. I do not use digoxin.

Q. Do you ever use KCl, potassium chloride, to cause fetal demise?

A. I can think of one or two cases where I have had to use potassium chloride to terminate the fetus prior to a procedure.

Q. But that is not generally part of your practice?

A. No.

[417]

Q. And why do you not use either of those chemicals to cause fetal demise?

A. I don't think either really add to the safety of the procedure of doing the D&E or doing an deduction of labor. And they do have some risks associated with them.

Q. What are the risks of digoxin, in your opinion?

A. And my opinion is, well, you have to do an amniocentesis to do digoxin. And an amniocentesis is not without risk. The risk is small, but it is not without risks. Main risks are bleeding and infection, with infection being the primary risk.

Q. Are there any other risks associated with the digoxin injection other than just because you have to do an amniocentesis?

A. I mean, theoretically, if you don't have the needle in the right place and you have it in the uterine wall you could get absorption of the digoxin into the maternal bloodstream. And that could potentially be dangerous to the woman.

In the study by Dr. Drey, it did not have enough patients to be able to tell whether—the frequency that this would occur, if really the dose is significant enough to be dangerous.

But, theoretically, yes, it is a risk for the patient.

Q. And you also indicated there were risks from infection in providing digoxin?

[418]

A. Only in that of the amniocentesis.

Q. And do you ever—do patients ever ask you whether there is something they could use to cause fetal demise?

A. Yes. I would—I don't know what percentage of my patients, but a certainly small number of patients ask could there be fetal demise prior to the procedure. When I talk to them about what it would entail to do, most of them do not want to proceed with that. And I don't think they are particularly worried about the effects. They don't think—I think about the infection risk.

They don't think about the infection risk. They just don't want to go through that procedure, to have a needle placed, and under ultrasound guidance maybe see the ultrasound and see the fetus again. The vast majority of the patients don't want to have that done.

Q. Are you able to—would you be able to give any patients digoxin if they wanted it?

A. It depends if I could do an amniocentesis on them, because that would be the method of administering them. And in some patients, amniocentesis could be very, very difficult to potentially impossible.

If there is a fetal condition where there is no amniotic fluid or the amniotic—there is premature rupture of membrane, and that is why we are doing it, it would be very, very difficult to inject the digoxin into the amniotic space if [419] the amniotic space is basically obliterated and the only thing there is the fetus.

Additionally, some patients are quite obese, and it would be very, very difficult to do amniocentesis on.

Q. And why is that?

A. Because visualization of where you have to be with ultrasound is very difficult because you have to look through a large adipose layer, through the skin, then the uterine wall, and then the uterine cavity.

Q. So there are some women for whom you could not do digoxin?

A. Yes.

Q. And are there—is there anybody else for whom the injection is technically difficult to do?

A. Some women it is really hard to predict, but do not image well with ultrasound. And being able to see where you need to go could be very, very difficult.

And I think it is more dangerous to potentially inject something where you don't know where it is if you are not in the correct space.

Q. Do any of your patients ever ask if the fetus experiences pain during the abortion procedure?

A. Yes, some patients ask that.

Q. And what do you tell them?

A. I tell them I don't know. I don't think—I don't know how anybody can know whether there is consciousness to the [420] point we have a realization of what pain is.

I tell them that I think it is unlikely that the fetus feels pain or has the ability to interpret painful stimuli as pain.

MS. PARKER: May I approach the witness, again, your Honor, to put up another blowup?

THE COURT: Yes.

BY MS. PARKER:

Q. Dr. Doe, I would like you to take a look at this blowup, which is the operative portion of the Partial-Birth Abortion Ban Act which is at issue in this case.

Have you seen that before?

A. Yes.

Q. And can you just read it to yourself for a moment?

Are you concerned about the potential impact of this law on your practice?

A. Yes.

Q. And what are your concerns?

A. My concerns are that it is unpredictable of whether I would sometimes deliver a fetus intact to the point that it's outside of the body of the mother, and that it might still be alive when I am doing kind of a standard D&E that I do.

Q. Does the term "Partial-Birth Abortion" have a commonly understood meaning in the medical community?

A. I don't think so, because I have talked to many of my [421] colleagues and they're always like:

"I am not sure what this procedure is."

MR. QUINLIVAN: Objection, hearsay.

THE COURT: Overruled.

BY MS. PARKER:

Q. Does the term "vaginally delivers," does that have a commonly understood meaning in the medical community?

A. Yes.

Q. And what is that meaning?

A. That the fetus delivers spontaneously through the cervix into the vagina and then out of the body.

Q. And does the term "a living fetus" have a commonly understood meaning?

A. Yes.

Q. And what is that meaning?

A. That the fetus has a beating heart.

Q. Is that the same thing as the fetus being viable?

A. No.

Q. What about the term—let's see:

"In the case of breech presentation any part of the fetal trunk past the navel is outside the body of the mother"?

What does that mean to you?

A. That would mean that the fetus is kind of delivered such that the majority of its body up to its umbilicus or navel is [422] outside of the vagina with the head potentially being still in the vagina or in the uterus.

Q. So in your opinion could this law be understood as banning some of the D&E's that you perform?

A. Yes.

Q. And that you would—where you would deliberately and intentionally vaginally deliver a living fetus until, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially-delivered living fetus?

A. Yes.

Q. And do you have concerns that you will violate the act—what are your concerns that you will be violating the act?

A. Well, again, some of my procedures of delivering the fetus wind up delivering intact to that point. I do not know if it is alive or not, but I might do maneuvers then to deliver the rest of the fetus, that if it were alive it certainly would then kill the fetus.

Q. And do you use your D&E procedures such that this could happen when you are handling a pregnancy termination which the patient had decided to do because of a maternal health condition?

A. Yes.

Q. And is that because most of your procedures are under those [423] circumstances?

A. Almost all of my procedures are of maternal health condition or a fetal abnormality.

* * * * *

[425]

* * * * *

Q. So, Dr. Doe, you indicated that this would have an impact on your practice; is that correct?

A. Yes.

Q. And what would that impact be on your current practice?

A. At this point I am currently going to stop doing D&E's, and I am going to discuss with counsel at the hospital what way I could potentially be protected, whether that is potentially joining NAFL or—

[426]

THE COURT: That is NAFL?

THE WITNESS: The National Abortion Federation League.

BY MS. PARKER:

Q. And why are you going to stop doing these procedures now?

A. Because I think it would be unpredictable for me to know whether I violate the act or not.

Q. Are you currently covered by the injunction?

A. In preparing for this case I found out that I am not covered by the injunction. I thought I was covered by the injunction, but I found out in preparing for the testimony for the trial that I am not covered by the injunction.

Q. And so as a result you are going to stop performing these procedures?

A. Yes.

* * * * *

[DR. DOE—CROSS EXAMINATION]

[430] and sometimes it's one visit.

So, my encounters with patients, the majority is not in the second trimester, but I see a large number of patients in the second-trimester.

Q. Is it fair to say, though, that in cases in which you perform abortions for either a fetal abnormality or a maternal condition, you perform them by both the D&E and the labor induction methods?

A. Yes.

Q. And is it fair to say you believe that both D&E and induction are safe methods of abortion?

A. Yes.

Q. I think you testified earlier, when asked, you tell your patients they are close to being essentially equal in terms of safety?

A. Yes.

Q. In fact, is it fair to say that you believe that both D&E and labor induction are extremely safe methods of abortion?

A. Yes.

Q. And you testified that in some cases of fetal abnormality, it's, important to do an autopsy of the fetus after an abortion is performed; is that correct?

A. Important, yes. If the couple is interested in recurrence information, and often they are.

Q. Can you—I am not sure you described that in your direct * * *?

* * * * *

[432]

* * * * *

Q. And I think you testified earlier that in about 15 percent of the D&E's you perform, the fetus is delivered partially intact so that the calvarium gets stuck in the cervix; is that correct?

A. It was—I think my testimony, I believe, is approximately 15 percent would be delivered intact. Not all of those that the calvarium would be stuck; some would deliver completely intact.

Q. Do you have a—can you give me an estimate of that 15 percent how many are delivered where the calvarium does get stuck in the cervix?

A. I would probably say at least 80 percent the calvarium would be stuck in the cervix.

Q. And just to be clear, the calvarium, again, is just the fetus' head, correct?

A. Correct.

* * * * *

[435]

Q. You mentioned there were some contraindications for labor induction when misoprostol is used; those contraindications wouldn't necessarily occur if oxytocin was used instead of misprostol; is that correct?

A. Well, not necessarily. It depends on what the indication for the contraindication is. If it's for the cardiac disease that I was talking about, no, oxytocin would not be a contraindication. But, however, for a previous hysterotomy, placenta previa, oxytocin would be a contraindication for labor induction.

Q. Thank you, Doctor.

Let me turn your attention to when you are performing a D&E abortion. Is it fair to say that disarticulation or dismemberment are common characteristics of a D&E?

A. Yes.

Q. And in performing a D&E procedure by disarticulation or dismemberment, you generally use forceps to remove the fetal parts?

A. Yes.

Q. You typically use what are known as bierer forceps?

A. Bierer forceps, yes. At earlier gestational ages I might use sopher forceps.

Q. And there are—is it fair to say that there are some unusual circumstances in which you might use hern or ring * * *.

* * * * *

[DR. DOE—REDIRECT EXAMINATION]

* * * * *

[457]

Q. Well, you offer your patients a choice of two methods of abortion during second-trimester; is that right?

A. Yes.

Q. And that is induction or a D&E abortion; is that right?

A. Correct.

Q. And approximately what percentage of patients choose to have a D&E procedure?

A. Approximately 75 percent of the patients choose to have a D&E procedure with the remainder 25 percent have an induction of labor.

Q. Why do the larger number of patients want to have a D&E procedure?

MR. QUINLIVAN: Objection, your Honor. That's speculation as to why—

THE COURT: Yes, unless he knows. If he knows, he may answer.

BY MS. PARKER:

Q. Do you know why more patients choose to have a D&E?

A. In many of the patients since I am the one counseling regarding the procedure and offering the options, they often tell me why they want to have one procedure or the other. I can't say in a hundred of the cases, but in many of the cases our interaction is such that:

"No, I want this procedure because."

And often they choose a D&E—again, the majority [458] of patients choosing D&E is because, one: they don't want to go through labor. It is something that when they have been diagnosed with one of these problems it is not something that they want to go through.

Two: often many of them are very worried about seeing the fetus, and they feel that they would do better without seeing the fetus.

Three, many of them don't want to spend the time in the hospital that it would take to have an induction of labor.

Those are the majority of the reasons.

Q. Now, Mr. Quinlivan had also asked you a series of questions About a disarticulation D&E versus an intact D&E. Do you recall those questions?

A. Yes.

Q. And the way you do the procedure, do you consider those two separate types of procedures?

A. The way I do the procedure, no, I do not. I think it is a variation of one. And it happens at an unpredictable rate, whether the fetus is intact or whether it is completely disarticulated.

Q. And when the fetus is able to emerge intact, you prefer that; isn't that right?

A. Yes.

Q. And why do you prefer it?

A. Because I think the risk of injury to the patient is less [459] because there are less passes of instruments into the uterine cavity in that situation.

Q. And less passes results in what?

A. In my clinical experience—and, again, if you extrapolate from other sudden studies, which may or may not be appropriate, but the fewer times you do something that has a potential risk, the lower likelihood of that risk.

* * * * *

[DR. DOE—CROSS EXAMINATION]

[464] patients under 22 weeks you would not recommend an injection of potassium chloride; is that right?

A. She did ask me that question, yes.

Q. Now, if a patient preferred or desired an injection of potassium chloride to ensure fetal demise prior to a procedure, you would give that to her, wouldn't you?

A. Yes.

MR. QUINLIVAN: Thank you. Nothing further.

THE COURT: All right. Anything else?

MS. PARKER: No, your honor.

THE COURT: Thank you, doctor. You are excused.

THE WITNESS: Thank you.

THE COURT: All right. Were there any other witnesses for the plaintiffs today?

MS. PARKER: No, your honor. Our next witness won't be available until Monday.

THE COURT: All right. And on Monday we have doctors Broekhuizen and Creinin?

MS. PARKER: Yes.

THE COURT: And then how long do you think—in addition to the regular trial day, how much additional time do you anticipate we would need to get through both of them on Monday?

MS. GARTNER: Your honor, I think it's hard to know until we actually meet with them over the weekend to do the * * *.

* * * * *

Supreme Court, U.S.
FILED
AUG 3 - 2006
OFFICE OF THE CLERK

No. 05-1382

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
PETITIONER

v.

PLANNED PARENTHOOD FEDERATION OF AMERICA,
INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JOINT APPENDIX
(VOLUME 2)

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PETITION FOR A WRIT OF CERTIORARI FILED: MAY 1, 2006
CERTIORARI GRANTED: JUNE 19, 2006

TABLE OF CONTENTS

Page

Volume 1

Court of appeals docket entries 1
District court docket entries 4
Trial testimony of Dr. Maureen Paul (Mar. 29, 2004) 13
Trial testimony of Dr. Katherine Sheehan (Mar. 29, 2004) 100
Trial testimony of Dr. Eleanor Drey (Mar. 30, 2004) 153
Trial testimony of Dr. Doe (Apr. 1, 2004) 191

Volume 2

Trial testimony of Dr. Frederick Brockhuizen (Apr. 5, 2004) 243
Trial testimony of Dr. Mitchell Creinin (Apr. 5, 2004) 338
Trial testimony of Dr. Carolyn Westhoff (Apr. 6, 2004) 415

Volume 3

Trial testimony of Dr. Stephen T. Chasen (Apr. 16, 2004) 463
Trial testimony of Dr. Watson Bowes, Jr. (Apr. 8, 2004) 543
Trial testimony of Dr. M. LeRoy Sprang (Apr. 9, 2004) 599

Volume 4

Trial testimony of Dr. Elizabeth Shadigian (Apr. 12, 2004) 676
Trial testimony of Dr. Curtis Cook (Apr. 13, 2004) 733
Trial testimony of Dr. Kanwaljeet S. Anand (Apr. 15, 2004) 789

TABLE OF CONTENTS—Continued: Page

Deposition of Dr. Joanna Cain (Feb. 10, 2004) [Redacted] 849
Deposition testimony of Dr. Steven L. Clark (Feb. 12, 2004) 862

Volume 5

Deposition testimony of Dr. Marilyn Conner Frederiksen (Feb. 17, 2004) 905
Deposition testimony of Dr. Amos Grunebaum (Feb. 2, 2004) 928
Deposition testimony of Dr. Cassing Hammond (Feb. 18, 2004) 941
Deposition testimony of Dr. Charles J. Lockwood (Feb. 17, 2004) 983
Deposition Exhibit (Plaintiffs' Exh. 6) 1039
Deposition testimony of Wan J. Kim (Feb. 13, 2004) 1040
Deposition testimony of William Moschella (Feb. 25, 2004) 1049
Stephen T. Chasen et al., *Dilation and Evacuation at ≥ 20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstetrics and Gynecology 1180 (2004) 1055 1061
Supplemental complaint (Nov. 13, 2003) 1071
Stipulation and order 1087

Volume 6
(UNDER SEAL)

Deposition of Dr. Joanna Cain (Feb. 10, 2004) [Unredacted] 1097

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

TRANSCRIPT OF PROCEEDINGS
Monday, Apr. 5, 2004
Volume 4

BEFORE THE HONORABLE
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* * * * *

[FREDERICK BROEKHUIZEN, M.D.—DIRECT EXAMINATION]

* * * * *

[482]

* * * * *

Q. Dr. Broekhuizen, are you board certified in obstetrics and gynecology?

A. Yes, I am.

Q. Can you please tell me the places where you are currently employed?

A. I am currently employed at the Medical College of Wisconsin, which is medical school located in Milwaukee for 80 percent of my time. The other 20 percent of my time I do international health consulting-teaching work.

And in the time that I am employed at the Medical College, 30 percent of that time there is an arrangement between Planned Parenthood of Wisconsin and the medical school to have me function as the part-time Medical Director of Planned Parenthood of Wisconsin.

[483]

Q. Okay. Can you describe your duties at the Medical College of Wisconsin, leaving aside a minute what you do at Planned Parenthood of Wisconsin?

A. I am a faculty member. I am a full Professor in Obstetrics and Gynecology. I have teaching duties teaching residents and medical students.

I will lecture. I participate in second and third-year courses of certain subjects. I have a clinical practice in general OB/GYN at the Medical College. And I am located for at least one third of my time in the Division of Internal Fetal Medicine where I do mainly management of high-risk obstetrical care and ultrasound and prenatal diagnosis.

Q. And do you deliver babies as part of your practice?

A. I certainly deliver babies as part of my practice.

Q. Do you have specific niches in which you have particular expertise?

A. Well, over the years I've kind of been involved in specific niches. I—for when I was in my previous employment, I was working in a city hospital and did a lot of public health-related activities, substance abuse and pregnancy, et cetera.

I have been for close to 24 years being the Medical Director of Planned Parenthood Colposcopy Clinics for patients with abnormal pap smears. And I've developed an interest in [484] cervical cancer, detection of the precursors of cervical cancer detection.

And some of my international work relates to the detection of early cervical cancer or precancer.

My international interest, as well, includes prevention of maternal mortality due to hemorrhage. And in the Milwaukee area over the last 24 years, one of my niches has been the provision of abortion services in hospital settings.

Q. And is there a particular hospital at which you generally practice medicine as a part of your work with the Medical College of Wisconsin?

A. Most of my clinical practice at the moment is located at Froedtert—it's a—I think it's called Froedtert Memorial Lutheran Hospital.

Q. Can you spell "Froedtert"?

A. F-r-o-e-d-t-e-r-t. I am on the medical staff of about eight hospitals in the Milwaukee area.

Q. And do you perform abortions at Froedtert Hospital?

A. I do.

Q. And under what circumstances do you perform abortions at Froedtert?

A. Froedtert Hospital has its own rules about what would be allowed for pregnancy terminations. The indications there would be lethal fetal anomalies or health conditions that would [485] pose a risk to the life of the mother.

Q. Can you explain what you mean by a "lethal fetal anomaly"?

A. That would be a fetal anomaly where there is no long term meaningful life expectancy. A death would be expected within hours to sometimes weeks.

Q. And how long have you been on the Faculty of the Medical College of Wisconsin?

A. Since January of 2001.

Q. And where were you before you joined the faculty at the Medical College of Wisconsin?

A. From the end of 1979 until January of 2001, I was a Faculty Member of the University of Wisconsin Medical School, which main campus is in Madison, Wisconsin, but they have a clinical campus which is located in Milwaukee.

Q. And were you ever the Chair of the Department at the Milwaukee campus at the University of Wisconsin?

A. I was the Chair of the Department of Obstetrics and Gynecology from 1989 until 1998.

Q. And where was—the Milwaukee campus of the University of Wisconsin, where was that located?

A. It was located at one of the hospitals in Milwaukee. Over the last 24 years, the name has

changed about four times. It started out to be Sinai Hospital. Then, it merged and became Sinai Samaritan Medical Center. And currently it called Aurora Sinai Medical Center.

[486]

Q. And at Aurora Sinai, did you provide abortions in a wider range of circumstances than you currently do at Froedtert?

A. Yes I have. And yes, I do. At Aurora Sinai Hospital there are no institution-based restrictions on the indications for a pregnancy termination.

Q. And when you say: "Yes, I do," does that mean that you still perform some abortions at Aurora Sinai?

A. I still perform some abortions at Aurora Sinai.

Q. Can you explain the circumstances in which you would do abortions currently at Aurora Sinai?

A. The majority of patients are referred to me by practicing OB/GYN physicians in the community or perinatologists in the State of Wisconsin.

And if I see the patient, confirm the diagnosis and come to a consensus with the patient that pregnancy termination is the proper thing to proceed with, the indications, that's the conditions, there are situations where I cannot perform that procedure at Froedtert Hospital for nonlethal fetal anomalies, as an example. And those patients then I will provide the services at Aurora Sinai Medical Center.

Q. And you testified that you are the part-time Medical Director of Planned Parenthood of Wisconsin; is that right?

A. That's correct.

Q. And can you describe your duties and medical practice at Planned Parenthood of Wisconsin?

[487]

A. Well, Planned Parenthood of Wisconsin has a little over 30 clinics across the state. As an example, there are six in Milwaukee. Most of the services at these Planned Parenthood clinics are family planning services and cervical cancer and breast cancer screening practices.

And mainly nurse practitioners who provide theseservices, I am their direct physician supervisor and provide a lot of consultations by e-mail and by phone.

I run a problem clinic for situations that nurse practitioners cannot handle within their scope of practice.

And then, I provided the colposcopy services. I am the head of a committee of associate medical directors/physicians. All the clinics have an associate local medical director. And we kind of set protocols, and quality of care standards for the provision of mainly family planning services.

Q. And are abortions performed at Planned Parenthood Wisconsin?

A. Two of those clinics have abortions are being performed.

Q. How late are abortions performed at those clinics?

A. Up until 16 weeks.

Q. And do you personally perform abortions at Planned Parenthood?

A. No, I don't.

Q. Why is that?

[488]

A. I list for you all my interest and my activities. And it is just a matter of choosing, you know, where I spend my time.

There are other physicians who provide the services, abortion services at the two planned parenthood clinics where abortions are being provided.

Q. How long have you been the Medical Director of Planned Parenthood?

A. Since sometime in 2001, shortly after I joined the Medical College.

Q. And did you provide medical services at Planned Parenthood before becoming the Medical Director?

A. Since 1980 I have been the Medical Director for their colposcopy services. And in many ways I have, you know, been on their advisory boards. And I have—I used to take medical students to Planned Parenthood clinics to teach them family planning.

Q. You said that you also do international health work. Can you describe that work?

A. I—many years ago I worked as a tropical physician in Ethiopia. And—but in the last five, six years I have done international consulting and training work for the World Health Organization, and mainly for an organization JHPIEGO. It's a John Hopkins affiliate that does training in reproductive health, projects in practice maternal and neonatal health and in cervical cancer prevention in several countries across the [489] world.

Q. And what countries have you been focusing on recently?

A. The last three years I have worked in Thailand, Ghana and Malawi.

Q. Dr. Broekhuizen, have you published in the area of obstetrics and gynecology?

A. Yes, I have.

Q. And, generally, what subject areas have you published in?

A. I have been—when I look at my curriculum vitae, I probably will identify the areas I was interested in in general obstetrics and gynecology and high-risk obstetrics at certain time, in human papilloma virus in relationship to precancer, cervical cancer detection.

And so it has been a pretty wide range and not one—all in one particular area.

Q. And are your publications all listed on your curriculum vitae?

A. They are all listed on my curriculum vitae.

Q. Do you do medical research in the field of obstetrics and gynecology?

A. I have been involved in two. I have conducted the randomized trial with one of my residents at the University of Wisconsin. I have been involved in two multicenter studies.

And, yes, I have been involved in different research projects.

Q. And Dr. Broekhuizen, what methods of abortion do you [490] currently perform in your practice?